



Bioventus LLC
4721 Emperor Blvd., Suite 100
Durham, NC 27703
USA

P 800.637.4391
F 888.279.0152
www.BioventusSurgical.com

Dear Materials Manager,

Bioventus LLC, a global leader in orthobiologics, is driven to deliver clinically proven, cost-effective products that help people heal quickly and safely. The Company's innovative products include market-leading devices and therapies that make it a global leader in active orthopaedic healing. Built on a commitment to high quality standards, evidence-based medicine, and strong ethical behavior, Bioventus is a trusted partner for physicians worldwide.

In keeping with these commitments, we are pleased to introduce the OSTEOAMP® platform of products. OSTEOAMP is a growth factor-rich bone graft substitute that is intended for homologous use for the repair, replacement, or reconstruction of musculoskeletal defects. Through proprietary methods, allograft bone and its native bone marrow are processed to preserve the naturally occurring bone morphogenetic proteins (BMP) and growth factors. The result is an osteoinductive product that fills the gap between traditional demineralized bone matrix (DBM) and recombinant human bone morphogenetic proteins (rhBMP-2). OSTEOAMP contains a wide array of naturally occurring growth factors including BMP-2, BMP-7, aFGF, and TGF-β1, relative to those reported in published literature for other allografts.¹⁻³

We invite you to learn more with the enclosed information or through our websites www.BioventusSurgical.com and www.OSTEOAMP.com.

Sincerely,

Bioventus Surgical

Enclosures

1. Thompson N and Govil A. Osteoinductivity and Osteogenicity of Leading Allograft Bone Products. 8th Combined Meeting of Orthopaedic Research Societies. Venice, Italy. October 13-16, 2013. 2. Chnari E, Javoroncov M, Gertzman AA, Sunwoo MH, Dunn MG. Bone Morphogenetic Protein 2 (BMP-2) Levels are Predictive of the Osteoinductive Potential of Demineralized Bone Matrix. Poster presented at: 56th Annual Meeting of the Orthopaedic Research Society; March 2010; New Orleans, LA. 3. Data on file RPT-000327; data from a single lot of OSTEOAMP sponge product.

Request for Taxpayer Identification Number and Certification

**Give Form to the
requester. Do not
send to the IRS.**

▶ Go to www.irs.gov/FormW9 for instructions and the latest information.

Print or type. See Specific Instructions on page 3.	<p>1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.</p> <p>BIOVENTUS LLC</p> <p>2 Business name/disregarded entity name, if different from above</p>	
	<p>3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes.</p> <p><input type="checkbox"/> Individual/sole proprietor or single-member LLC <input type="checkbox"/> C Corporation <input type="checkbox"/> S Corporation <input type="checkbox"/> Partnership <input type="checkbox"/> Trust/estate</p> <p><input checked="" type="checkbox"/> Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ <u> P </u></p> <p>Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.</p> <p><input type="checkbox"/> Other (see instructions) ▶</p>	<p>4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):</p> <p>Exempt payee code (if any) _____</p> <p>Exemption from FATCA reporting code (if any) _____</p> <p><small>(Applies to accounts maintained outside the U.S.)</small></p>
	<p>5 Address (number, street, and apt. or suite no.) See instructions.</p> <p>4721 EMPEROR BLVD STE 100</p> <p>6 City, state, and ZIP code</p> <p>DURHAM NC 27703</p> <p>7 List account number(s) here (optional)</p>	<p>Requester's name and address (optional)</p>

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number									
or									
Employer identification number									
4	5	-	3	9	3	5	6	2	8

Part II Certification

Under penalties of perjury, I certify that:

- The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
- I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
- I am a U.S. citizen or other U.S. person (defined below); and
- The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here	Signature of U.S. person ▶ <i>Keri Shah</i>	Date ▶ <i>1/12/2018</i>
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General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to www.irs.gov/FormW9.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, later.

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EXEMPTION FROM FDA TISSUE ESTABLISHMENT LICENSURE

Per the Code of Federal Regulations (CFR) Title 21 Part 1271.1 (b)(1), the FDA requires registration and listing of establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under the authority of section 361 of the Public Health Service Act.

As outlined in 21 CFR Part 1271.3(e) 'manufacture' is defined as: "any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor"

Bioventus does not perform any of the aforementioned activities.


All HCT/Ps marketed by Bioventus are manufactured by licensed tissue banks. The fully-manufactured HCT/Ps are supplied to our third-party logistics supplier who manages the storage and distribution of Bioventus' HCT/Ps. Our third-party logistics supplier is also a registered tissue establishment.

Bioventus handles orders for sales of HCT/Ps by hospitals and other medical facilities; however, Bioventus is expressly excluded from the specific regulatory definition of distributor in the context of the regulation, 21 CFR Part 1271.3(bb) which states: "If an entity does not take physical possession of an HCT/P, the entity is not considered a distributor." (Emphasis added.)

Bioventus does not take physical possession of any HCT/Ps at any time. Accordingly, Bioventus is not required to register with the FDA as a tissue establishment.

Establishment registrations for Bioventus suppliers who manufacture or distribute HCT/Ps may be found in the following FDA tissue establishment registration database:

<https://www.accessdata.fda.gov/scripts/cber/CFAppsPub/tiss/index.cfm>



Signature



Date

MK Kottke
Director, Regulatory and Clinical Affairs
Bioventus Surgical

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3007499718	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA: 27-NOV-2017 DISTRICT: New Orleans PRINTED BY FDA: 27-JAN-2018										
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps					11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)				
		Establishment Functions												
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Millstone Medical Outsourcing 8836 Polk Lane Suite 100 Olive Branch, Mississippi 38654 a. PHONE 508-679-8384 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone				X		X	X	X	X	X		See Text on Next Page
		b. Cartilage												
		c. Cornea												
		d. Dura Mater												
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		f. Fascia												
		g. Heart Valve												
5. ENTER CORRECTIONS TO ITEM 4		h. Ligament				X		X	X	X	X	X		
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		j. Pericardium												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Millstone Medical Outsourcing Attn: Kelly J. Lucenti 580 Commerce Drive Fall River, Massachusetts 02720 a. PHONE 508-679-8384 EXT 2026		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		l. Sclera												
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE 508-679-8384 EXT 2026 b. PHONE _____		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		n. Skin				X		X	X	X	X	X		HuMend; DermaSpan; DermaSpan Mesh
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
8. U.S. AGENT a. E-MAIL _____		p. Tendon				X		X	X	X	X	X		
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		r. Vascular Graft												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Kelly J. Lucenti b. E-MAIL klucenti@millstonemedical.com c. TITLE President d. DATE 27-NOV-2017		s. Amniotic Membrane				X		X	X	X	X	X		BioFix; Amniofix
		t. Placenta				X		X	X	X	X	X		BioFix
		u. Amniotic Fluid				X		X	X	X	X			AmnioFlo
		v.												



Dear Tissue Bank Director:

Attached below is your tissue bank license.
Your license is void after the expiration date.

NOTE: Applications for renewal of license must be filed with the department **not less than 30 days** prior to its expiration date and shall be accompanied by the annual renewal fee. (CA H&S Code §1639.2)

**MILLSTONE MEDICAL OUTSOURCING, LLC
8836 POLK LN STE 100
ATTN: SCOTT JONES, QUALITY DEPT
OLIVE BRANCH MS 38654-7812**

FORFEITURE OF LICENSE

A Tissue Bank license shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

QUESTIONS AND INFORMATION:

If you have any questions, please write to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
Laboratory Field Services, Tissue Bank Section
850 Marina Bay Parkway, Building P, 1st Floor
Richmond, CA 94804-6403

Internet Address: www.cdph.ca.gov/LFS

Thank you for your cooperation.

TB 100 TBLIC (4-16)

Tear Here

Tear Here

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed tissue bank operation(s) at the indicated facility address.

**MILLSTONE MEDICAL OUTSOURCING, LLC
8836 POLK LANE, STE 100
OLIVE BRANCH MS 38654**

OWNER(S):
MILLSTONE MEDICAL OUTSOURCING, LLC
SCHOONER PRIVATE EQUITY, LLC

DIRECTOR(S):
MICHAEL SCOTT JONES

TISSUE BANK ID Number: CTB 00080809
Issuance Date: July 1, 2018
Expiration Date: June 30, 2019

Robert J. Thomas
Robert J. Thomas, Acting Branch Chief
Laboratory Field Services

STATE OF CONNECTICUT ♦ DEPARTMENT OF CONSUMER PROTECTION

Be it known that

MILLSTONE MEDICAL OUTSOURCING LLC

8836 POLK LN STE 100

OLIVE BRANCH, MS 38654-7812

has satisfied the qualifications required by law and is hereby issued a

WHOLESALE OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: No Rx Legend Drugs: No Non Rx Legend Drugs: Yes Medical Devices: Yes
Cosmetics: No Medical Gases/Oxygen: No Durable Medical Equipment (DME): Yes

Registration #: CSW.0002406

Effective Date: 07/01/2018

Expiration Date: 06/30/2019

verify online at www.elicense.ct.gov



Michelle Seagull, Commissioner



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

Monday, March 12, 2018

Patricia Pope
Millstone Medical Outsourcing, LLC
Olive Branch, MS 38654

Dear **Patricia Pope**,

This letter confirms that **Millstone Medical Outsourcing, LLC** is registered with the Delaware Tissue Bank until April 30, 2019.

Thank you for notifying the Bureau of Communicable Diseases office in a timely manner of any changes to the information contained in the registration form. Please continue to keep contact information current to ensure timely delivery of updates and notifications.

If you have any questions, please contact me at the number below, or via my e-mail.

Best regards,

Martin Luta MD

Chief, Bureau of Communicable Diseases

Delaware Department of Health and Social Services

Division of Public Health

Thomas Collins Building

540 South DuPont Highway, Dover, DE 19901

Office: 302-744-1050

FAX: 302-739-2549

martin.luta@state.de.us

View current license information at: Floridahealthfinder.gov

LICENSE #: 166
CERTIFICATE #: 1237

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
Tissue Bank

Licensed

This is to confirm that Millstone Medical Outsourcing Llc has complied with the requirements of the State of Florida, Agency for Health Care Administration, for certification as authorized by Florida Statutes 765.542 and is to operate the following:

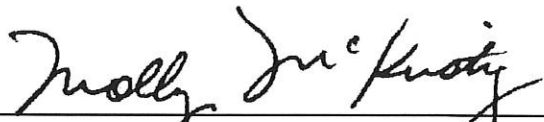
MILLSTONE MEDICAL OUTSOURCING LLC
8836 Polk Lane Ste 100
Olive Branch, MS 38654

Authorized Services: distribute tissues

EFFECTIVE DATE: 10/28/2016

EXPIRATION DATE: 10/27/2018




Deputy Secretary, Division of Health Quality Assurance



525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Effective Date: May 1, 2018

Expires: May 01, 2019

Patricia Pope, Facility Director
Millstone Medical Outsourcing, LLC
8836 Polk Lane, Suite 100
Olive Branch, MS 38654

Registration Number 0110

State of Illinois
2018
Sperm And Tissue
Establishment Registration

Millstone Medical Outsourcing, LLC

Dear Director:

We are in receipt of your 2018 Registration with the State of Illinois. We welcome your cooperation to observe our State laws and you may use this document as proof of registration as required by *Title 77 Public Health Chapter 1: Department of Public Health Subchapter D: Laboratories and Blood Bank Part 470 Sperm Bank and Tissue Bank Code Section 470.30 Registration Requirements.*

Sincerely,

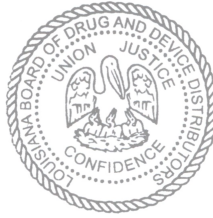


Juan Garcia
Tissue & Sperm Bank
Program Administrator
Illinois Department of Public Health
Health Care Facilities and Programs
Laboratory Regulations

Annual registration deadline is May 1, and renewal reminders are e-mailed on February of each year.

PROTECTING HEALTH. IMPROVING LIVES

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS



DISTRIBUTOR OF LEGEND DRUGS OR LEGEND DEVICES

SUB-TYPE: Third-Party Logistic Provider Distributor

MILLSTONE MEDICAL OUTSOURCING, LLC

License No. **7477** effective **01/01/2018** (Original issue date: 01/02/2013), Expiring **12/31/2018**

distributing from **8836 Polk Lane, Suite 100, Olive Branch, MS, 38654**

BUSINESS ADDRESS: 8836 POLK LANE, SUITE 100, OLIVE BRANCH, MS, 38654

is duly licensed in the State of Louisiana with this Board under the provisions of Act 852 of 1988 (as amended).

This license is subject to regulation in the state of Louisiana

in accordance with La. R.S. 37:3461 through 3482 and LAC 46:XXXIV.101 through 1503.

Additional Third-Party Logistics Providers:

NA

Board Secretary

ORIGINAL LICENSE — DISTRIBUTOR

This License is NOT TRANSFERABLE and must be Conspicuously Displayed. This license must be renewed annually.

Louisiana Board of Drug and Device Distributors
12091 Bricksome Avenue, Suite B
Baton Rouge, LA 70816

Phone: 225-295-8567
Fax: 225-295-8568

www.lsbwdd.org
Email: admin@lsbwdd.org

SUB-TYPES:

Standard Distributor: Any entity that sales or facilitates the delivery of legend drugs or legend devices to persons other than the consumer or patient; including, but not limited to, manufacturers, repackagers, own-label distributors, jobbers, retail pharmacy warehouses, pharmacies, brokers, agents, freight forwarders, ship chandlers, reverse distributors, compounders/503b, and nuclear pharmacies.

Wholesale Distributor: Any entity that sales or facilitates the delivery of drug product (as defined by FDA) to persons other than the consumer or patient; not to include (not limited to) manufacturers, repackagers, third-party logistic providers, distributors of devices, medical gases, intravenous drugs for replenishment or irrigation, blood or blood components; radioactive drugs or biologicals, imaging drugs, homeopathic drugs, and compounded drugs.

Third-party Logistics Provider: Any entity that provides or coordinates warehousing, facilitates the delivery of, or other logistic services for a legend drug or legend device interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend drug or legend device.



MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY

SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

TISSUE BANK PERMIT

NUMBER: TB1858 EFFECTIVE PERIOD: 07/01/2018 - 06/30/2020

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

MILLSTONE MEDICAL OUTSOURCING LLC
8836 POLK LANE STE 100
OLIVE BRANCH, MS 38654

Director: Dr MICHAEL BAGWELL

Owner: SCHOONER PRIVATE EQUITY, LLC

For operating, representing or servicing the following Tissue Bank Classes:

Musculoskeletal Tissue Bank:

Bone, Demineralized Bone Matrix, Ligament, Musculoskeletal Tissue, Tendons

Reproductive Tissue Bank:

Embryo, Epididymal Aspirates, Ovarian Tissue, Preimplantation Genetic Testing, Reproductive Tissue, Sperm,
Testicular Tissue

CONTROL: 70328

Patricia Tomsko May, MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: TP163TS125

Tissue Bank Director:
Patricia M. Pope, Ph.D.
Quality Assurance Specialist

Medical Director:
Perry C. Rothrock, M.D.

Millstone Medical Outsourcing, L.L.C.
8836 Polk Lane, Suite 100
Olive Branch, MS 38654

is hereby **APPROVED** as a Tissue Bank for the following categories of service:

Tissue Processing Facility
Tissue Storage Facility

Musculoskeletal tissue
Musculoskeletal tissue
Amniotic membrane

Issued: February 19, 2016

Owner: Millstone Medical Outsourcing, L.L.C.

Expires: March 1, 2020

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2001)



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 305
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)

January 8, 2016

Ms. Patricia Pope, Administrator
Millstone Medical Outsourcing, LLC
8836 Polk Lane, Suite 100
Olive Branch, MS 38654

Dear Ms. Pope:

This letter is to notify you that Millstone Medical Outsourcing, LLC has been renewed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on January 26, 2019.

Thank you for your cooperation. Should you have any questions, please call me at the above phone number.

Sincerely,

A handwritten signature in cursive script that reads "Jane Gardner".

Jane Gardner
Licensing and Certification Specialist
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY (971) 673-0372.

**OREGON REVISED STATUTES
2007**

441.079 Eye, organ and tissue transplants. (1) As used in this section and ORS 441.082:

(a) "Entity" means an individual, corporation, business trust, partnership, limited liability company, association, joint venture or an instrumentality of an entity.

(b) "Eye bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes or parts of human eyes.

(c) "Health care facility" has the meaning given that term in ORS 442.015.

(d) "Organ procurement organization" means an entity designated by the United States Secretary of Health and Human Services as an organ procurement organization.

(e) "Tissue bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of tissue for transplants.

(2) Tissue banks and eye banks must be registered with and regulated by the United States Food and Drug Administration.

(3) A health care facility that performs organ transplants must:

(a) Be a member of the Organ Procurement and Transplantation Network established by the National Organ Transplant Act of 1984;

(b) Be regulated by the United States Department of Health and Human Services; and

(c) Use an organ procurement organization to obtain organs for transplants.

(4) A health care facility that performs tissue or corneal transplants must obtain the tissue or corneas from a tissue bank or an eye bank that is registered with and regulated by the United States Food and Drug Administration. [2007 c.334 §1]

Note: 441.079 and 441.082 were enacted into law by the Legislative Assembly but were not added to or made a part of ORS chapter 441 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

441.080 [Repealed by 1971 c.730 §25]

441.081 [1979 c.680 §2; repealed by 1981 c.784 §38]

441.082 Registration of organ procurement organization, tissue bank and eye bank; rules; penalties. (1) The Department of Human Services shall adopt by rule standards and a system of registration for every organ procurement organization, tissue bank and eye bank doing business in this state.

(2) An organ procurement organization, tissue bank or eye bank may not do business in this state unless it has registered with the department.

(3) Each organ procurement organization, tissue bank and eye bank shall provide to the department at least every three years current documentation of designation, certification and inspection as evidence of compliance with national standards and requirements under federal law.

(4) The department may impose a civil penalty not to exceed \$1,000 against an organ procurement organization, tissue bank or eye bank doing business in this state for failure to:

(a) Register with the department;

(b) Report loss of designation, accreditation or certification within 60 days of the loss; or
(c) Supply the department with requested current documentation of designation, certification and inspection.

(5) Civil penalties under this section shall be imposed in the manner provided under ORS 183.745. [2007 c.334 §2]

Note: 441.082 becomes operative July 1, 2008. See section 4, chapter 334, Oregon Laws 2007.

Note: See note under 441.079.

Note: Section 3, chapter 334, Oregon Laws 2007, provides:

Sec. 3. Each organ procurement organization, tissue bank and eye bank doing business in this state must register with the Department of Human Services within 30 days after the operative date [July 1, 2008] of section 2 of this 2007 Act [441.082]. [2007 c.334 §3]

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3008769422	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:21-NOV-2017 DISTRICT: Los Angeles PRINTED BY FDA:27-JAN-2018																																																																																																																																																																																																																																																																																																																																																																																										
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____ 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Advanced Biologics, LLC 2800 Roosevelt Street Carlsbad, California 92008 a. PHONE 800-272-0267 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2" style="writing-mode: vertical-rl; transform: rotate(180deg);">11. 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5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Advanced Biologics, LLC Attn: Jesse Adawag 2800 Roosevelt Street Carlsbad, California 92008 a. PHONE 800-272-0267 EXT 704	7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____		8. U.S. AGENT a. E-MAIL _____																																																																																																																																																																																																																																																																																																																																																																																										
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Jesse Adawag b. E-MAIL jadawag@advancedbiologics.com c. TITLE Manager, Quality & Regulatory d. DATE 21-NOV-2017																																																																																																																																																																																																																																																																																																																																																																																													

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3008769422

ADDITIONAL INFORMATION:

Annual registration renewal for FEI: 3008769422.

Proprietary Name(s):



Dear Tissue Bank Director:

Attached below is your tissue bank license.
Your license is void after the expiration date.

NOTE: Applications for renewal of license must be filed with the department **not less than 30 days** prior to its expiration date and shall be accompanied by the annual renewal fee. (CA H&S Code §1639.2)

ADVANCED BIOLOGICS
2800 ROOSEVELT ST
ATTN: JESSE ADAWAG
CARLSBAD CA 92008-1619

FORFEITURE OF LICENSE

A Tissue Bank license shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

QUESTIONS AND INFORMATION:

If you have any questions, please write to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
Laboratory Field Services, Tissue Bank Section
850 Marina Bay Parkway, Building P, 1st Floor
Richmond, CA 94804-6403

Internet Address: www.cdph.ca.gov/LFS
Thank you for your cooperation.

TB 100 TBLC (4-16)

Tear Here

Tear Here

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed tissue bank operation(s) at the indicated facility address.

ADVANCED BIOLOGICS
2800 ROOSEVELT ST.
CARLSBAD CA 92008

OWNER(S):

AMIT GOVIL
SCOTT CADOTTE
SPINALGENICS, LLC

DIRECTOR(S):

AMIT GOVIL

TISSUE BANK ID Number: CTB 00080844

Issuance Date: June 24, 2018

Expiration Date: June 23, 2019

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

Wednesday, March 21, 2018

Jesse Adawag
Advanced Biologics, LLC
Carlsbad, CA 92008

Dear **Jesse Adawag**,

This letter confirms that **Advanced Biologics, LLC** is registered with the Delaware Tissue Bank until April 30, 2019.

Thank you for notifying the Bureau of Communicable Diseases office in a timely manner of any changes to the information contained in the registration form. Please continue to keep contact information current to ensure timely delivery of updates and notifications.

If you have any questions, please contact me at the number below, or via my e-mail.

Best regards,

Martin Luta MD

Chief, Bureau of Communicable Diseases

Delaware Department of Health and Social Services

Division of Public Health

Thomas Collins Building

540 South DuPont Highway, Dover, DE 19901

Office: 302-744-1050

FAX: 302-739-2549

martin.luta@state.de.us

View current license information at: Floridahealthfinder.gov

LICENSE #: 265
CERTIFICATE #: 1371

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
Tissue Bank

Licensed

This is to confirm that Advanced Biologics, LLC has complied with the requirements of the State of Florida, Agency for Health Care Administration, for certification as authorized by Florida Statutes 765.542 and is to operate the following:

ADVANCED BIOLOGICS LLC
2800 Roosevelt St
Carlsbad, CA 92008

Authorized Services: distribute tissues

EFFECTIVE DATE: 04/20/2018

EXPIRATION DATE: 04/19/2020



Molly McKinstry
Deputy Secretary, Division of Health Quality Assurance



525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Effective Date: **May 1, 2018**

Expires: **May 01, 2019**

Amit Govil, Facility Director
Advanced Biologics, LLC
2800 Roosevelt Street
Carlsbad, CA 92008

Registration Number **2214**

State of Illinois
2018
Sperm And Tissue
Establishment Registration

Advanced Biologics, LLC

Dear Director:

We are in receipt of your 2018 Registration with the State of Illinois. We welcome your cooperation to observe our State laws and you may use this document as proof of registration as required by *Title 77 Public Health Chapter 1: Department of Public Health Subchapter D: Laboratories and Blood Bank Part 470 Sperm Bank and Tissue Bank Code Section 470.30 Registration Requirements.*

Sincerely,



Juan Garcia
Tissue & Sperm Bank
Program Administrator
Illinois Department of Public Health
Health Care Facilities and Programs
Laboratory Regulations

Annual registration deadline is May 1, and renewal reminders are e-mailed on February of each year.



MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY

SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

TISSUE BANK PERMIT

NUMBER: TB1763 EFFECTIVE PERIOD: 07/01/2018 - 06/30/2020

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

**ADVANCED BIOLOGICS, LLC
2800 ROOSEVELT STREET
CARLSBAD, CA 92008**

**Director: Dr R TRIGG MCCLELLAN
Owner: ADVANCED BIOLOGICS, LLC**

For operating, representing or servicing the following Tissue Bank Classes:

Musculoskeletal Tissue Bank:
Bone, Demineralized Bone Matrix

CONTROL: 69953

Patricia Tomsko May, MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

NEW YORK STATE DEPARTMENT OF HEALTH

PROVISIONAL LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: TS130

Director:
Amit Govil
President

Medical Director:
R. Trigg McClellan, M.D.

Advanced Biologics, L.L.C. and Biologica Technologies, L.L.C.
2800 Roosevelt Street
Carlsbad, CA 92008

is hereby APPROVED as a Tissue Bank for the following categories of service:

Tissue Storage Facility

Musculoskeletal tissue
Skin tissue

Issued: March 2, 2018

Owner: Advanced Biologics, L.L.C. and Biologica Technologies, L.L.C.

Expires: April 1, 2020

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2001)



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)

January 27, 2017

 **FILE**

Mr. Amit Govil
Advanced Biologics
2800 Roosevelt Street
Carlsbad, CA 92008

Dear Mr. Govil:

This letter is to notify you that Advanced Biologics has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on February 15, 2020.

Should you have any questions, please call (971) 673-0540 or via email at mailbox.hclc@state.or.us.

Sincerely,

A handwritten signature in black ink that reads "Catherine B. Cook".

Catherine B. Cook
Licensing Specialist
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

American Association of Tissue Banks

*Herewith certifies
that the Institution named here*

Community Tissue Services - Dayton Dayton, Ohio

*has met the Association's accreditation requirements and
is hereby accredited for Donor Eligibility Assessment and
Authorization; Recovery, Processing, Release, Storage, and
Distribution of Skin and Musculoskeletal Tissue for Transplantation;
Recovery of Cardiac and Vascular Tissue for Transplantation; and Storage
and Distribution of Autologous Tissue for Transplantation*

November 9, 2016 – November 9, 2019

*In witness whereof the undersigned officers, being duly authorized, have caused this Certificate to be issued and the
Corporate Seal of this Association to be affixed hereon this the 25th day of July 2017*



Dan Schott

Chairman

John L. ...

President & Chief Executive Officer

Accreditation # 00035/9 (Revised)



American Association of Tissue Banks®

July 25, 2017

Patty Malone
Director, Quality/Regulatory Affairs
Community Tissue Services - Dayton
349 South Main Street
Dayton, OH 45402

Dear Ms. Malone:

On behalf of the Board of Governors, I am pleased to inform you that the American Association of Tissue Banks (AATB) has approved Community Tissue Services - Dayton for accreditation after you had successfully addressed the nonconformities resulting from the inspection. The accreditation covers Donor Eligibility Assessment and Authorization; Recovery, Processing, Release, Storage and Distribution of Skin and Musculoskeletal Tissue for Transplantation; Recovery of Cardiac and Vascular Tissue for Transplantation; and Storage and Distribution of Autologous Tissue for Transplantation. Obtaining accreditation by the Association is a most important accomplishment, and we congratulate you and your staff.

The mission of the AATB is to improve and save lives by promoting the safety, quality, and availability of donated human tissue. Our Accreditation Program helps to realize this goal by checking that tissue-banking activities are being performed in an ethical and professional manner consistent with the AATB's *Standards*.

In addition to the special recognition attendant to AATB Accreditation, additional benefits include the following:

- Staff members may attend AATB meetings and workshops at reduced rates;
- Your tissue bank will receive a complimentary copy of future *AATB Standards for Tissue Banking*, when available;
- You may also purchase publications at the membership rate and;
- You may use the AATB Accredited Institution Logo (contact Jason LoVerdi at loverdij@aatb.org for logo and information).

Visit our web site at www.aatb.org to see how you can become involved in the various activities of the AATB.

Your accreditation will expire on November 9, 2019. It will be your responsibility to note this date and re-apply in a manner consistent with the current version of AATB's *Accreditation Policies for Transplant Tissue Banks*. You should request the accreditation application approximately 12 months prior to the expiration of your accreditation and you must submit the completed application no later than nine months prior to the accreditation expiration date.

Please accept our sincerest congratulations on your accreditation. We look forward to your participation in and support of the Association's activities. If there is ever any way in which we can assist you, I hope that you will not hesitate to contact us.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Frank S. Wilton', is written over a faint, larger version of the same signature.

Frank S. Wilton
President & Chief Executive Officer

Accreditation #00035/9; Accreditation Date: November 9, 2016 (REVISED)
Attached: Certificate



American Association of Tissue Banks®

November 23, 2016

Patty Malone
Director, Quality/Regulatory Affairs
Community Tissue Services - Dayton
349 South Main Street
Dayton, OH 45402

Dear Ms. Malone:

This letter accompanies the accreditation certificate for Community Tissue Services - Dayton to include the accreditation of the following satellite facilities:

Center for Tissue Innovation and Research
2900 College Drive
Kettering, OH 45420

Community Tissue Services – California
7100 New Financial Drive, Suite 105
Fresno, CA 93720

Community Tissue Services – Mid-South
1790 Kirby Parkway, Suite 130
Memphis, TN 38138

Community Tissue Services – Pennsylvania
6573 Bristol Pike, Suite 201
Bensalem, PA 19020

Community Tissue Services – Texas
328 South Adams Street
Fort Worth, TX 76104

Refer to: Accreditation #00035/9, Accreditation Date: November 9, 2016

Sincerely,

A handwritten signature in black ink, appearing to read 'Jason E. LoVerdi', written over a white background.

Jason E. LoVerdi, MHA, CTBS
Accreditation Manager



Dear Tissue Bank Director:

Attached below is your tissue bank license.
Your license is void after the expiration date.

NOTE: Applications for renewal of license must be filed with the department **not less than 30 days** prior to its expiration date and shall be accompanied by the annual renewal fee. (CA H&S Code §1639.2)

**COMMUNITY TISSUE SERVICES - OHIO
2900 COLLEGE DR
ATTN: PATTY MALONE
KETTERING OH 45420-2972**

FORFEITURE OF LICENSE

A Tissue Bank license shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

QUESTIONS AND INFORMATION:

If you have any questions, please write to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
Laboratory Field Services, Tissue Bank Section
850 Marina Bay Parkway, Building P, 1st Floor
Richmond, CA 94804-6403

Internet Address: www.cdph.ca.gov/LFS

Thank you for your cooperation.

TB 100 TBLC (4-16)

Tear Here

Tear Here

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed tissue bank operation(s) at the indicated facility address.

**COMMUNITY TISSUE SERVICES - OHIO
2900 COLLEGE DRIVE
KETTERING OH 45420**

OWNER(S):
COMMUNITY TISSUE SERVICES

DIRECTOR(S):
DIANE WILSON

TISSUE BANK ID Number: CTB 00080312

Issuance Date: June 25, 2018

Expiration Date: June 24, 2019

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

Thursday, April 19, 2018

Patty Malone
Community Tissue Services--Dayton
Dayton, OH 45402

Dear **Patty Malone**,

This letter confirms that **Community Tissue Services—Dayton** is registered with the Delaware Tissue Bank until April 30, 2019.

Thank you for notifying the Bureau of Communicable Diseases office in a timely manner of any changes to the information contained in the registration form. Please continue to keep contact information current to ensure timely delivery of updates and notifications.

If you have any questions, please contact me at the number below, or via my e-mail.

Best regards,

Martin Luta MD

Chief, Bureau of Communicable Diseases
Delaware Department of Health and Social Services
Division of Public Health
Thomas Collins Building
540 South DuPont Highway, Dover, DE 19901
Office: 302-744-1050
FAX: 302-739-2549
martin.luta@state.de.us

View current license information at: Floridahealthfinder.gov

LICENSE #: 41
CERTIFICATE #: 1232

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
Tissue Bank

Licensed

This is to confirm that Community Blood Center has complied with the requirements of the State of Florida, Agency for Health Care Administration, for certification as authorized by Florida Statutes 765.542 and is to operate the following:

COMMUNITY TISSUE SERVICES

2900 College Dr
Kettering, OH 45420

Authorized Services: distribute tissues

EFFECTIVE DATE: 11/03/2016

EXPIRATION DATE: 11/02/2018



Molly McKeon
Deputy Secretary, Division of Health Quality Assurance



525-535 West Jefferson Street • Springfield, Illinois 62761-0001 • www.dph.illinois.gov

Effective Date: **May 1, 2018**

Expires: **May 01, 2019**

Diane Wilson, Facility Director
Community Blood Center
D/B/A Community Tissue Services
2900 College Drive
Kettering, OH 45420

Registration Number **0911**

State of Illinois
2018
Sperm And Tissue
Establishment Registration

Community Blood Center D/B/A Community Tissue Services

Dear Director:

We are in receipt of your 2018 Registration with the State of Illinois. We welcome your cooperation to observe our State laws and you may use this document as proof of registration as required by *Title 77 Public Health Chapter I: Department of Public Health Subchapter D: Laboratories and Blood Bank Part 470 Sperm Bank and Tissue Bank Code Section 470.30 Registration Requirements.*

Sincerely,



Juan Garcia
Tissue & Sperm Bank
Program Administrator
Illinois Department of Public Health
Health Care Facilities and Programs
Laboratory Regulations

Annual registration deadline is May 1, and renewal reminders are e-mailed on February of each year.



MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY

SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

TISSUE BANK PERMIT

NUMBER: TB1145 EFFECTIVE PERIOD: 07/01/2018 - 06/30/2020

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

**Community Tissue Services
2900 COLLEGE DRIVE
KETTERING, OH 45420**

**Director: Dr DAVID SMITH
Owner: DAVID SMITH, MD**

For operating, representing or servicing the following Tissue Bank Classes:

Musculoskeletal Tissue Bank:

Musculoskeletal Tissue

Skin Bank:

Skin

CONTROL: 70007

Patricia Tomsko May, MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: CP151

Tissue Bank Director:

**Diane L. Wilson, RN, CTBS
Chief Operating Officer**

Medical Director:

James L. Alexander, M.D.

Community Tissue Services - Dayton

**349 S. Main Street
Dayton, OH 45402**

is hereby APPROVED as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service

**Musculoskeletal Tissue
Skin Tissue
Pericardium**

Issued: August 4, 2017

Owner: Community Blood Center

Expires: September 1, 2021

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)

July 25, 2017

Ms. Diane Wilson
Community Tissue Services
349 S Main St
Dayton, OH 45402

Dear Ms. Wilson:

This letter is to notify you that Community Tissue Services - Dayton has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on September 29, 2020.

Should you have any questions, please call (971) 673-0540.

Sincerely,

A handwritten signature in blue ink that reads "Catherine B. Cook".

Catherine B. Cook
Licensing Specialist
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711

American Association of Tissue Banks

*Herewith certifies
that the Institution named here*

DCI Donor Services Tissue Bank Nashville, Tennessee

*has met the Association's accreditation requirements and
is hereby accredited for Donor Eligibility Assessment,
Processing, Release, Storage, and Distribution of Skin,
Musculoskeletal, and Birth Tissue Transplantation*

November 16, 2017 – December 6, 2020

*In witness whereof the undersigned officers, being duly authorized, have caused this Certificate to be issued and the
Corporate Seal of this Association to be affixed hereon this the 8th day of December 2017*



James E. Barnes III

Chairman

J. Sawicki
President & Chief Executive Officer

Accreditation # #00088/8

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 1000307504	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:22-NOV-2017 DISTRICT: New Orleans PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION														14. PROPRIETARY NAME(S)	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS				
	Establishment Functions															
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute							
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) DCI Donor Services Tissue Bank 1714 Hayes Street Nashville, Tennessee 37203 a. PHONE 615-234-5200 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone		X		X	X	X	X	X	X						
	b. Cartilage		X		X	X	X	X	X	X						
	c. Cornea															
	d. Dura Mater															
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	f. Fascia			X		X	X	X	X	X	X					
	g. Heart Valve															
	h. Ligament			X		X	X	X	X	X	X					
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	j. Pericardium			X		X	X	X	X	X	X					
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) DCI Donor Services Attn: Carrie S. Crocker, BA, CTBS 1714 Hayes Street Nashville, Tennessee 37203 a. PHONE 615-564-3774 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	l. Sclera															
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	n. Skin			X		X	X	X	X	X	X					
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	p. Tendon			X		X	X	X	X	X	X					
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	r. Vascular Graft															
	s. Amniotic Membrane			X		X	X	X	X	X	X					
	t.															
8. U.S. AGENT a. E-MAIL _____	u.															
	v.															
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Carrie S. Crocker, BA, CTBS b. E-MAIL ccrocker@dcids.org c. TITLE Sr. Director, GTP Quality Systems d. DATE 22-NOV-2017																



Dear Tissue Bank Director:

Attached below is your tissue bank license.
Your license is void after the expiration date.

NOTE: Applications for renewal of license must be filed with the department **not less than 30 days** prior to its expiration date and shall be accompanied by the annual renewal fee. (CA H&S Code §1639.2)

DCI DONOR SERVICES, INC.
1714 HAYES ST
ATTN: SUSAN PRIDE
NASHVILLE TN 37203-3013

FORFEITURE OF LICENSE

A Tissue Bank license shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

QUESTIONS AND INFORMATION:

If you have any questions, please write to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
Laboratory Field Services, Tissue Bank Section
850 Marina Bay Parkway, Building P, 1st Floor
Richmond, CA 94804-6403

Internet Address: www.cdph.ca.gov/LFS

Thank you for your cooperation.

TB 100 TB LIC (4-16)

Tear Here

Tear Here

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed tissue bank operation(s) at the indicated facility address.

DCI DONOR SERVICES, INC.
308 15TH AVENUE NORTH
NASHVILLE TN 37203

OWNER(S):

DCI DONOR SERVICES, INC.

DIRECTOR(S):

CARRIE CROCKER

TISSUE BANK ID Number: CTB 00080539

Issuance Date: September 5, 2018

Expiration Date: September 4, 2019

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services



Dear Tissue Bank Director:

Attached below is your tissue bank license.
Your license is void after the expiration date.

NOTE: Applications for renewal of license must be filed with the department **not less than 30 days** prior to its expiration date and shall be accompanied by the annual renewal fee. (CA H&S Code §1639.2)

DCI DONOR SERVICES, INC.
1714 HAYES ST
ATTN: SUSAN PRIDE
NASHVILLE TN 37203-3013

FORFEITURE OF LICENSE

A Tissue Bank license shall be forfeited by operation of law prior to its expiration date when one of the following occurs:

- (1) The tissue bank is sold or otherwise transferred.
- (2) The license is surrendered to the state department.

QUESTIONS AND INFORMATION:

If you have any questions, please write to:

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
Laboratory Field Services, Tissue Bank Section
850 Marina Bay Parkway, Building P, 1st Floor
Richmond, CA 94804-6403

Internet Address: www.cdph.ca.gov/LFS
Thank you for your cooperation.

TB 100 TB LIC (4-16)

Tear Here

Tear Here

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed tissue bank operation(s) at the indicated facility address.

DCI DONOR SERVICES, INC.
1714 HAYES STREET
NASHVILLE TN 37203

OWNER(S):

DCI DONOR SERVICES, INC.

DIRECTOR(S):

CARRIE CROCKER

TISSUE BANK ID Number: CTB 00080538

Issuance Date: September 5, 2018

Expiration Date: September 4, 2019

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services

View current license information at: Floridahealthfinder.gov

LICENSE #: 53
CERTIFICATE #: 1334

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
Tissue Bank

Licensed

This is to confirm that Dci Donor Services has complied with the requirements of the State of Florida, Agency for Health Care Administration, for certification as authorized by Florida Statutes 765.542 and is to operate the following:

DCI DONOR SERVICES
1714 Hayes Street
Nashville, TN 37203

Authorized Services: distribute tissues

EFFECTIVE DATE: 11/07/2017

EXPIRATION DATE: 10/25/2019



Molly McKeon
Deputy Secretary, Division of Health Quality Assurance



RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

November 7, 2017

Administrator
DCI Donor Services
1714 Hayes Street
Nashville, TN 37203

File Number: 41950085
License Number: 53
Provider Type: Organ and Tissue
Procurement

RE: 1714 Hayes Street, Nashville

Dear Administrator:

The enclosed Organ and Tissue Procurement license with license number 53 and certificate number 1334 is issued for the above provider effective November 7, 2017 through October 25, 2019. The license is being issued for: approval of the renewal application.

Review your certificate thoroughly to ensure that all information is correct and consistent with your records. If errors are noted, please contact the Laboratory Licensure Unit.

Please take a short customer satisfaction survey on our website at ahca.myflorida.com/survey/ to let us know how we can serve you better. Additional licensure information can be found at <http://ahca.myflorida.com/labs>.

If we may be of further assistance, please contact me by phone at (850) 412-4373 or by email at Linda.Lovette-Leonard@ahca.myflorida.com.

Sincerely,

Linda Lovette-Leonard
Health Services & Facilities Consultant
Laboratory Licensure Unit
Division of Health Quality Assurance





**MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY**

SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

TISSUE BANK PERMIT

NUMBER: TB1640 EFFECTIVE PERIOD: 07/01/2017 - 06/30/2019

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

**DCI DONOR SERVICES
1714 HAYES STREET
NASHVILLE, TN 37203**

**Director: HARRISON SHULL JR MD
Owner: DCI DONOR SERVICES, INC.**

For operating, representing or servicing the following Tissue Bank Classes:

Musculoskeletal Tissue Bank:

Bone, Cartilage, Cultured Tissue, Demineralized Bone Matrix, Fascia Lata, Ligament, Musculoskeletal Tissue,
Tendons

Skin Bank:

Skin

CONTROL: 67439

Patricia Tomsko May, MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: CP098TP077

Tissue Bank Director:
Kelly R. Snyder, M.S., C.T.B.S.

Medical Director:
Robert E. Richie, M.D.

DCI Donor Services
1714 Hayes Street
Nashville, TN 37203

is hereby **APPROVED** as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service

Musculoskeletal tissue
Skin tissue
Pericardium
Placentas/amniotic membrane

Tissue Processing Facility

Musculoskeletal tissue
Skin tissue
Pericardium
Amniotic membrane

Issued: April 22, 2016

Expires: March 1, 2020

Owner: DCI Donor Services, Inc.

DOH-3908 (04/2001)

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: CP108TP078

Tissue Bank Director:

Kelly R. Snyder, M.S., C.T.B.S.

Medical Director:

Robert E. Richie, M.D.

DCI Donor Services

308 15th Avenue North

Nashville, TN 37203

is hereby **APPROVED** as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service

Musculoskeletal tissue

Skin tissue

Pericardium

Tissue Processing Facility

Musculoskeletal tissue

Skin tissue

Pericardium

Issued: August 19, 2016

Owner: DCI Donor Services

Expires: September 1, 2020

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2004)



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)

March 15, 2017

Ms. Carrie Crocker
DCI Donor Services
1714 Hayes Street
Nashville, TN 37203

Dear Ms. Crocker:

This letter is to notify you that DCI Donor Services has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on April 14, 2020.

Should you have any questions, please call (971) 673-0540 or via email to mailbox.hclc@state.or.us.

Sincerely,

A handwritten signature in black ink that reads "Catherine B. Cook". The signature is written in a cursive style.

Catherine B. Cook
Licensing Specialist
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711

**OREGON REVISED STATUTES
2007**

441.079 Eye, organ and tissue transplants. (1) As used in this section and ORS 441.082:

(a) "Entity" means an individual, corporation, business trust, partnership, limited liability company, association, joint venture or an instrumentality of an entity.

(b) "Eye bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes or parts of human eyes.

(c) "Health care facility" has the meaning given that term in ORS 442.015.

(d) "Organ procurement organization" means an entity designated by the United States Secretary of Health and Human Services as an organ procurement organization.

(e) "Tissue bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of tissue for transplants.

(2) Tissue banks and eye banks must be registered with and regulated by the United States Food and Drug Administration.

(3) A health care facility that performs organ transplants must:

(a) Be a member of the Organ Procurement and Transplantation Network established by the National Organ Transplant Act of 1984;

(b) Be regulated by the United States Department of Health and Human Services; and

(c) Use an organ procurement organization to obtain organs for transplants.

(4) A health care facility that performs tissue or corneal transplants must obtain the tissue or corneas from a tissue bank or an eye bank that is registered with and regulated by the United States Food and Drug Administration. [2007 c.334 §1]

Note: 441.079 and 441.082 were enacted into law by the Legislative Assembly but were not added to or made a part of ORS chapter 441 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

441.080 [Repealed by 1971 c.730 §25]

441.081 [1979 c.680 §2; repealed by 1981 c.784 §38]

441.082 Registration of organ procurement organization, tissue bank and eye bank; rules; penalties. (1) The Department of Human Services shall adopt by rule standards and a system of registration for every organ procurement organization, tissue bank and eye bank doing business in this state.

(2) An organ procurement organization, tissue bank or eye bank may not do business in this state unless it has registered with the department.

(3) Each organ procurement organization, tissue bank and eye bank shall provide to the department at least every three years current documentation of designation, certification and inspection as evidence of compliance with national standards and requirements under federal law.

(4) The department may impose a civil penalty not to exceed \$1,000 against an organ procurement organization, tissue bank or eye bank doing business in this state for failure to:

(a) Register with the department;

(b) Report loss of designation, accreditation or certification within 60 days of the loss; or

(c) Supply the department with requested current documentation of designation, certification and inspection.

(5) Civil penalties under this section shall be imposed in the manner provided under ORS 183.745. [2007 c.334 §2]

Note: 441.082 becomes operative July 1, 2008. See section 4, chapter 334, Oregon Laws 2007.

Note: See note under 441.079.

Note: Section 3, chapter 334, Oregon Laws 2007, provides:

Sec. 3. Each organ procurement organization, tissue bank and eye bank doing business in this state must register with the Department of Human Services within 30 days after the operative date [July 1, 2008] of section 2 of this 2007 Act [441.082]. [2007 c.334 §3]

American Association of Tissue Banks

*Herewith certifies
that the Institution named here*

LifeLink Tissue Bank Tampa, Florida

*has met the Association's accreditation requirements and is hereby
accredited for Donor Eligibility Assessment and Authorization;
Recovery, Processing, Release, Storage, and Distribution of
Musculoskeletal Tissue for Transplantation; Recovery of Skin,
Cardiac, and Vascular Tissue for Transplantation; and Processing,
Storage, and Distribution of Autologous Tissue for Transplantation*

April 17, 2017 – April 19, 2020

*In witness whereof the undersigned officers, being duly authorized, have caused this Certificate to be issued and the
Corporate Seal of this Association to be affixed hereon this the 1st day of May 2017*



Daniel Schott

Chairman

J. S. S. S.

President & Chief Executive Officer

Accreditation # 00039/9



American Association of Tissue Banks®

May 1, 2017

Liz Horn-Brinson
Vice President, Quality Assurance
LifeLink Tissue Bank
9661 Delaney Creek Blvd.
Tampa, FL 33619

Dear Ms. Horn-Brinson:

This letter accompanies the accreditation certificate for LifeLink Tissue Bank to include the accreditation of the following satellite facilities:

LifeLink Tissue Bank - Orlando

1729 South Orange Avenue
Orlando, FL 32806

LifeLink of Georgia

2875 Northwoods Parkway
Norcross, GA 30071

LifeLink of Puerto Rico

Chrysler Building / Metro Office Park
1 Calle 1
Suite 100
Guaynabo, PR 00968

Refer to: Accreditation #00039/9, Accreditation Date: April 17, 2017

Sincerely,

A handwritten signature in black ink, appearing to read 'Jason E. LoVerdi', is written over a white background.

Jason E. LoVerdi, MHA, CTBS
Vice President of Accreditation

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3003474667	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:29-NOV-2017 DISTRICT: Atlanta PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Establishment Functions												
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lifelink of Georgia (Atlanta Office) 2875 Northwoods Pkwy Norcross, Georgia 30071 a. PHONE 800-544-6667 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X				X	X	X	X			
	b. Cartilage	X	X				X	X	X	X			
	c. Cornea												
	d. Dura Mater												
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	f. Fascia	X	X				X	X	X	X			
	g. Heart Valve	X	X							X			
	h. Ligament	X	X				X	X	X	X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium	X	X				X	X	X	X			
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	l. Sclera												
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
5. ENTER CORRECTIONS TO ITEM 4	n. Skin	X	X							X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) LifeLink of Georgia Attn: Kathy Lilly 2875 Northwoods Pkwy Norcross, Georgia 30071 a. PHONE 800-544-6667 EXT _____	p. Tendon	X	X				X	X	X	X			
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE _____ b. PHONE _____	r. Vascular Graft	X	X							X			
8. U.S. AGENT a. E-MAIL _____	s.												
	t.												
	u.												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Kathy Lilly b. E-MAIL kathleen.lilly@lifelinkfound.org c. TITLE Exec. V.P. OPO Operation/ Exec. Director d. DATE 29-NOV-2017	v.												

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3007197601	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:21-NOV-2017 DISTRICT: Florida PRINTED BY FDA:27-JAN-2018
---	--	--	--

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION														14. PROPRIETARY NAME(S)	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS				
	Establishment Functions															
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute							
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) LifeLink Tissue Bank - Orlando 1743 South Orange Ave. Orlando, Florida 32806 a. PHONE 407-218-8783 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone						X	X	X	X					LifeGraft, TruArc, LifeFlex	
	b. Cartilage						X	X	X	X						
	c. Cornea															
	d. Dura Mater															
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	f. Fascia						X	X	X	X						
	g. Heart Valve															
	h. Ligament						X	X	X	X						
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	j. Pericardium															
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) LifeLink Tissue Bank Attn: Elizabeth S. Horn-Brinson, BS 9661 Delaney Creek Boulevard Tampa, Florida 33619 a. PHONE 813-804-4325 EXT 4325 b. PHONE _____	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	l. Sclera															
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous															
	n. Skin															
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	p. Tendon						X	X	X	X						
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	r. Vascular Graft															
	7. ENTER CORRECTIONS TO ITEM 6 8. U.S. AGENT a. E-MAIL _____	s.														
		t.														
u.																
v.																
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Elizabeth S. Horn-Brinson, BS b. E-MAIL liz.brinson@lifelinkfound.org c. TITLE VP, QA d. DATE 20-NOV-2017																

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3001238470	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:21-NOV-2017 DISTRICT: San Juan PRINTED BY FDA:27-JAN-2018
---	--	--	---

PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION													14. PROPRIETARY NAME(S)		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps								11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS					
	Types of HCT / Ps		Establishment Functions													
			Recover	Screen	Test	Package	Process	Store	Label	Distribute						
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lifelink of Puerto Rico Daimler-Chrysler Bldg./Metro Office Park 1 Calle 1 , Suite 100 Guaynabo, Puerto Rico 00968-1711 a. PHONE 800-558-0977 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone		X	X							X					
	b. Cartilage		X	X							X					
	c. Cornea															
	d. Dura Mater															
	e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	f. Fascia		X	X								X				
	g. Heart Valve		X	X								X				
	h. Ligament		X	X								X				
	i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	j. Pericardium		X	X								X				
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) LifeLink Tissue Bank Attn: Elizabeth S. Horn-Brinson 9661 Delaney Creek Boulevard Tampa, Florida 33619 a. PHONE 813-804-4325 EXT 4325	k. Peripheral Blood Stem	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	l. Sclera															
	m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	n. Skin															
	o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	p. Tendon		X	X								X				
	q. Umbilical Cord Blood	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	r. Vascular Graft		X	X								X				
	s.															
	t.															
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	u.															
	v.															
8. U.S. AGENT a. E-MAIL _____																
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Elizabeth S. Horn-Brinson b. E-MAIL liz.brinson@lifelinkfound.org c. TITLE VP, QA d. DATE 20-NOV-2017																

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed tissue bank operation(s) at the indicated facility address.

LIFELINK TISSUE BANK
9661 DELANEY CREEK BLVD.
TAMPA FL 33619

OWNER(S):

LIFELINK FOUNDATION, INC

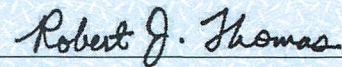
DIRECTOR(S):

MARK STRONG

TISSUE BANK ID Number: CTB 00080225

Issuance Date: December 29, 2017

Expiration Date: December 28, 2018



Robert J. Thomas, Acting Branch Chief
Laboratory Field Services



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

Friday, February 16, 2018

Elizabeth Horn-Brinson
LifeLink Tissue Bank
Tampa, FL 33619

Dear **Elizabeth Horn-Brinson**,

This letter confirms that **LifeLink Tissue Bank** is registered with the Delaware Tissue Bank until April 30, 2019.

Thank you for notifying the Bureau of Communicable Diseases office in a timely manner of any changes to the information contained in the registration form. Please continue to keep contact information current to ensure timely delivery of updates and notifications.

If you have any questions, please contact me at the number below or via my e-mail.

Best regards,

Martin Luta MD

Chief, Bureau of Communicable Diseases

Delaware Department of Health and Social Services

Division of Public Health

Thomas Collins Building

540 South DuPont Highway, Dover, DE 19901

Office: 302-744-1050

FAX: 302-739-2549

martin.luta@state.de.us

View current license information at: Floridahealthfinder.gov

LICENSE #: 163
CERTIFICATE #: 1408

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
Tissue Bank

Licensed

This is to confirm that Lifelink Foundation Inc. has complied with the requirements of the State of Florida, Agency for Health Care Administration, for certification as authorized by Florida Statutes 765.542 and is to operate the following:

LIFELINK TISSUE BANK
9661 Delaney Creek Blvd
Tampa, FL 33619

Authorized Services: recover, process, distribute and storage tissues

EFFECTIVE DATE: 08/17/2018

EXPIRATION DATE: 08/16/2020



Molly McKeon
Deputy Secretary, Division of Health Quality Assurance

View current license information at: Floridahealthfinder.gov

LICENSE #: 155
CERTIFICATE #: 1363

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
Tissue Bank

Licensed

This is to confirm that Lifelink Foundation Inc. has complied with the requirements of the State of Florida, Agency for Health Care Administration, for certification as authorized by Florida Statutes 765.542 and is to operate the following:

LIFELINK TISSUE BANK - ORLANDO

1743 S Orange Ave
Orlando, FL 32806

Authorized Services: distribute and storage tissues

EFFECTIVE DATE: 03/09/2018

EXPIRATION DATE: 03/08/2020



Molly McKeon
Deputy Secretary, Division of Health Quality Assurance



MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY

SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

TISSUE BANK PERMIT

NUMBER: TB1375 EFFECTIVE PERIOD: 07/01/2018 - 06/30/2020

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

LIFELINK FOUNDATION TISSUE BANK
9661 DELANEY CREEK
TAMPA, FL 33619

Director: Dr DANIEL SCHULTZ
Owner: LIFELINK FOUNDATION

For operating, representing or servicing the following Tissue Bank Classes:

Musculoskeletal Tissue Bank:

Bone, Cartilage, Demineralized Bone Matrix, Fascia Lata, Ligament, Musculoskeletal Tissue, Tendons

CONTROL: 70037

Patricia Tomsko May, MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: CP147TP112

Tissue Bank Director:
Dana L. Shires, III
Executive Director/Sr. Vice President

Medical Director:
Daniel L. Schultz, M.D.

LifeLink Tissue Bank
9661 Delaney Creek Boulevard
Tampa, FL 33619

is hereby APPROVED as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service

Cardiovascular tissue
Musculoskeletal tissue
Skin tissue

Tissue Processing Facility

Cardiovascular tissue
Musculoskeletal tissue
Skin tissue

Issued: June 19, 2015

Expires: July 1, 2019

Owner: LifeLink Tissue Bank

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)

December 6, 2017

Ms. Elizabeth Horn-Brinson
Lifelink Tissue Bank
9661 Delaney Creek Blvd
Tampa, FL 33619

Dear Ms. Horn-Brinson:

This letter is to notify you that Lifelink Tissue Bank has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on January 11, 2021.

Should you have any questions, please call (971) 673-0540.

Sincerely,

A handwritten signature in blue ink that reads "Catherine B. Cook".

Catherine B. Cook
Licensing Specialist
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711



American Association of Tissue Banks®

July 19, 2018

Dan Mahaffey, MBA, RAC
Director of Regulatory Affairs and Quality Assurance
Pinnacle Transplant Technologies, LLC
1125 West Pinnacle Peak Road
Phoenix, AZ 85027

Dear Mr. Mahaffey:

This letter serves to confirm an accreditation extension for Pinnacle Transplant Technologies, LLC. Pinnacle Transplant Technologies, LLC will have continued AATB accreditation until September 30, 2018, as all requirements and timelines have been met during the re-accreditation process.

This letter also serves to confirm that it is best practice to verify a tissue bank's current accreditation status by accessing the AATB website to perform a relevant, real-time, accredited tissue bank search by using the "Accredited Bank Search" function.

We appreciate your participation in this important program of the Association. If you have any questions or need additional information, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jason E. LoVerdi', is written over a light gray rectangular background.

Jason E. LoVerdi, MHA, CTBS
Vice President of Accreditation

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3008927553	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:17-NOV-2017 DISTRICT: Los Angeles PRINTED BY FDA:14-DEC-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION								11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
	Types of HCT / Ps	Establishment Functions											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3008927553 c. DRUG FDA 2656 NO. _____	a. Bone		X	X	X	X	X	X	X	X			*** See full text on next page
	b. Cartilage		X	X	X	X	X	X	X	X			
	c. Cornea												
	d. Dura Mater												
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	f. Fascia		X	X	X	X	X	X	X	X			
	g. Heart Valve												
	h. Ligament		X	X	X	X	X	X	X	X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium												
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	l. Sclera												
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	n. Skin		X	X	X	X	X	X	X	X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	p. Tendon		X	X	X	X	X	X	X	X			
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft												
	s. Amniotic Membrane		X	X	X	X	X	X	X	X			*** See full text on next page
	t. Adipose Tissue		X	X	X	X	X	X	X	X			Allofill
	u. Amniotic Fluid		X	X	X	X	X	X	X	X			*** See full text on next page
	v. Bone Marrow Aspirate		X	X	X	X	X	X	X	X			ProteiOS

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3008927553

2

ADDITIONAL INFORMATION:

Proprietary Name(s):

a. Bone Apex DBM Putty, Apex Crunch, Apex Fiber, Apex
FP, Apex FP Plus, Ossif-istem (tm)

Amniotic Palingen Membrane, Palingen Hydromembrane,
Membrane Palingen XPlus Hydromembrane, Kardia Membrane,
SX Barrier, ASGFluid,

Amniotic Fluid Amnio Biologix, AmnioFlex, SX Fluid, SX
Matrix,Palingen Flow, Palingen SportFlow, Promatrix
ACF, KardiaFlow, Nanofactor,

STATE OF CALIFORNIA DEPARTMENT OF PUBLIC HEALTH
TISSUE BANK LICENSE

In accordance with Division 2, Chapter 4.1, of the Health and Safety Code, the entity named below is hereby licensed to engage in the listed tissue bank operation(s) at the indicated facility address.

PINNACLE TRANSPLANT TECHNOLOGIES, LLC
1125 W. PINNACLE PEAK RD BLDG #2 STE 116
PHOENIX AZ 85027

OWNER(S):

PINNACLE TRANSPLANT TECHNOLOGIES, LLC
GABRIEL R. HYAMS

DIRECTOR(S):

GABRIEL HYAMS

TISSUE BANK ID Number: CTB 00080893

Issuance Date: November 30, 2017

Expiration Date: November 29, 2018

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services



**DELAWARE HEALTH
AND SOCIAL SERVICES**

DIVISION OF PUBLIC HEALTH

Monday, April 02, 2018

Danielle Cox
Pinnacle Transplant Technologies, LLC
Phoenix, AZ 85027

Dear **Danielle Cox**,

This letter confirms that **Pinnacle Transplant Technologies, LLC** is registered with the Delaware Tissue Bank until April 30, 2019.

Thank you for notifying the Bureau of Communicable Diseases office in a timely manner of any changes to the information contained in the registration form. Please continue to keep contact information current to ensure timely delivery of updates and notifications.

If you have any questions, please contact me at the number below, or via my e-mail.

Best regards,

Martin Luta MD

Chief, Bureau of Communicable Diseases
Delaware Department of Health and Social Services
Division of Public Health
Thomas Collins Building
540 South DuPont Highway, Dover, DE 19901
Office: 302-744-1050
FAX: 302-739-2549
martin.luta@state.de.us

View current license information at: Floridahealthfinder.gov

LICENSE #: 184
CERTIFICATE #: 1365

State of Florida
AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE
Tissue Bank

Licensed

This is to confirm that Pinnacle Transplant Technologies LLC has complied with the requirements of the State of Florida, Agency for Health Care Administration, for certification as authorized by Florida Statutes 765.542 and is to operate the following:

PINNACLE TRANSPLANT TECHNOLOGIES LLC

1125 W Pinnacle Peak Rd
Bldg. 2
Phoenix, AZ 85027-1401

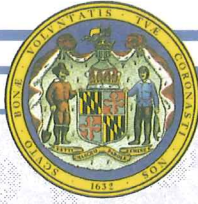
Authorized Services: distribute tissues

EFFECTIVE DATE: 02/01/2018

EXPIRATION DATE: 01/23/2020



Molly McKinstry
Deputy Secretary, Division of Health Quality Assurance



MARYLAND
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF HEALTH CARE QUALITY

SPRING GROVE CENTER
BLAND BRYANT BUILDING
55 WADE AVENUE
CATONSVILLE, MD 21228-4663

TISSUE BANK PERMIT

NUMBER: TB1870 EFFECTIVE PERIOD: 07/01/2018 - 06/30/2020

*Pursuant to the provisions of TITLE 17, subtitle 3, Health-General Article § 17-301 et seq.,
Annotated Code of Maryland, this permit is issued to:*

PINNACLE TRANSPLANT TECHNOLOGIES LLC
1125 W PINNACLE PEAK RD BLDG 2
PHOENIX, AZ 85027

Director: Dr MICHAEL BAUER

Owner: GABRIEL HYAMS

For operating, representing or servicing the following Tissue Bank Classes:

Progenitor Cell Bank:

Placental Derived

Musculoskeletal Tissue Bank:

Bone, Demineralized Bone Matrix, Fascia Lata, Ligament, Musculoskeletal Tissue, Tendons

Skin Bank:

Dermis, Skin

CONTROL: 70089

Patricia Tomsko May, MD

Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the imposition of civil fines.

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: CP158TP127

Tissue Bank Director:
Gabriel R. Hyams
President/Executive Director

Medical Director:
Dennis L. Furr, M.D.

Pinnacle Transplant Technologies, L.L.C.
1125 West Pinnacle Peak Road, Building 2
Phoenix, AZ 85027

is hereby APPROVED as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service

Musculoskeletal tissue
Skin tissue

Tissue Processing Facility

Musculoskeletal tissue
Skin tissue

Issued: March 17, 2017

Owner: Pinnacle Transplant Technologies, L.L.C.

Expires: April 1, 2021

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

NEW YORK STATE DEPARTMENT OF HEALTH

LICENSE FOR TISSUE BANK OPERATION

Issued in accordance with and pursuant to section 4364 Public Health Law of New York State

Tissue Bank ID No.: CP158TP127

Tissue Bank Director:
Gabriel R. Hyams
President/Executive Director

Medical Director:
Dennis L. Furr, M.D.

Pinnacle Transplant Technologies, L.L.C.
1125 West Pinnacle Peak Road, Building 2
Phoenix, AZ 85027

is hereby **APPROVED** as a Tissue Bank for the following categories of service:

Comprehensive Tissue Procurement Service

Musculoskeletal tissue
Skin tissue

Tissue Processing Facility

Musculoskeletal tissue
Skin tissue

Issued: March 17, 2017

Owner: Pinnacle Transplant Technologies, L.L.C.

Expires: April 1, 2021

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.

DOH-3908 (04/2001)



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)

March 20, 2018

Mr. Gabriel Hyams
Pinnacle Transplant Technologies, LLC
1125 W Pinnacle Peak Rd, Bldg #2
Phoenix, AZ 85027

Dear Mr. Hyams:

This letter is to notify you that Pinnacle Transplant Technologies, LLC has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on March 20, 2021.

Should you have any questions, please call (971) 673-0540 or via email to mailbox.hclc@state.or.us.

Sincerely,

A handwritten signature in blue ink that reads "Catherine B. Cook".

Catherine B. Cook
Licensing Specialist
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

If you need this information in an alternate format, please call our office at (971) 673-0540 or TTY 711

**OREGON REVISED STATUTES
2007**

441.079 Eye, organ and tissue transplants. (1) As used in this section and ORS 441.082:

(a) "Entity" means an individual, corporation, business trust, partnership, limited liability company, association, joint venture or an instrumentality of an entity.

(b) "Eye bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of human eyes or parts of human eyes.

(c) "Health care facility" has the meaning given that term in ORS 442.015.

(d) "Organ procurement organization" means an entity designated by the United States Secretary of Health and Human Services as an organ procurement organization.

(e) "Tissue bank" means an entity that is licensed or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage or distribution of tissue for transplants.

(2) Tissue banks and eye banks must be registered with and regulated by the United States Food and Drug Administration.

(3) A health care facility that performs organ transplants must:

(a) Be a member of the Organ Procurement and Transplantation Network established by the National Organ Transplant Act of 1984;

(b) Be regulated by the United States Department of Health and Human Services; and

(c) Use an organ procurement organization to obtain organs for transplants.

(4) A health care facility that performs tissue or corneal transplants must obtain the tissue or corneas from a tissue bank or an eye bank that is registered with and regulated by the United States Food and Drug Administration. [2007 c.334 §1]

Note: 441.079 and 441.082 were enacted into law by the Legislative Assembly but were not added to or made a part of ORS chapter 441 or any series therein by legislative action. See Preface to Oregon Revised Statutes for further explanation.

441.080 [Repealed by 1971 c.730 §25]

441.081 [1979 c.680 §2; repealed by 1981 c.784 §38]

441.082 Registration of organ procurement organization, tissue bank

and eye bank; rules; penalties. (1) The Department of Human Services shall adopt by rule standards and a system of registration for every organ procurement organization, tissue bank and eye bank doing business in this state.

(2) An organ procurement organization, tissue bank or eye bank may not do business in this state unless it has registered with the department.

(3) Each organ procurement organization, tissue bank and eye bank shall provide to the department at least every three years current documentation of designation, certification and inspection as evidence of compliance with national standards and requirements under federal law.

(4) The department may impose a civil penalty not to exceed \$1,000 against an organ procurement organization, tissue bank or eye bank doing business in this state for failure to:

(a) Register with the department;

(b) Report loss of designation, accreditation or certification within 60 days of the loss; or

(c) Supply the department with requested current documentation of designation, certification and inspection.

(5) Civil penalties under this section shall be imposed in the manner provided under ORS 183.745. [2007 c.334 §2]

Note: 441.082 becomes operative July 1, 2008. See section 4, chapter 334, Oregon Laws 2007.

Note: See note under 441.079.

Note: Section 3, chapter 334, Oregon Laws 2007, provides:

Sec. 3. Each organ procurement organization, tissue bank and eye bank doing business in this state must register with the Department of Human Services within 30 days after the operative date [July 1, 2008] of section 2 of this 2007 Act [441.082]. [2007 c.334 §3]