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

Request for Taxpayer Identification Number and Certification

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

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

1. Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.

   BIOVENTUS LLC

2. Business name/disregarded entity name, if different from above

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.
   - Individual/sole proprietor or single-member LLC
   - C Corporation
   - S Corporation
   - Partnership
   - Trust/state

   Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶

   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.

4. Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):
   - Exempt payee code (if any) ▶
   - Exemption from FATCA reporting code (if any) ▶

   (Applies to accounts maintained outside the U.S.)

5. Address (number, street, and apt. or suite no.) See instructions.

   4721 EMPEROR BLVD STE 100

6. City, state, and ZIP code

   DURHAM NC 27703

   List account number(s) here (optional)

   Requester's name and address (optional)

   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 name to enter.

   Social security number

   or

   Employer identification number

   453935628

   Part II  Certification

   Under penalties of perjury, I certify that:

   1. 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

   2. 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 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 ▶

   Date 1/12/2018

   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 1098 (proceeds from real estate transactions)
   - Form 1098-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.
Table of Certification

Bioventus LLC

Bioventus Exemption from FDA Tissue Establishment Licensure........................................5

Distributor: Millstone Medical Outsourcing

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Supplier: Advanced Biologics, LLC

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Tissue Banks

Community Tissue Services

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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:


MK Kottke
Director, Regulatory and Clinical Affairs
Bioventus Surgical
### Legal Name and Location:
Millstone Medical Outsourcing
8836 Polk Lane
Suite 100
Olive Branch, Mississippi 38654
USA
Phone: 508-679-8384 Ext. 2026
klucenti@millstonemedical.com

### Reporting Official:
Kelly J Lucenti, President
580 Commerce Drive
Fall River, Massachusetts 02720
USA
Phone: 508-679-8384 Ext. 2026
klucenti@millstonemedical.com

### Other FDA Registrations:

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### Reason For Last Submission:
Annual Registration/Listing

### Last Annual Registration Year:
2018

### Last Registration Receipt Date:
07/19/2018

### Summary Report Print Date:
11/15/2018

### FEI:
3007499718

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Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
Additional Information: Proprietary Names:

a. Bone: Osteoamp; Purebone; Exponent; Allograft Bone Wedge; SeaSpine Capistrano Cervical Spacer; SeaSpine PLIF Allograft; SeaSpine Compressible Bone Matrix; SeaSpine Cervical Allograft; Laminoplasty Cortical Allograft; Bi-OSETETIC BLOCK; LESBiologics; DBMForm; FacetFuse; Alto-Span; Allogenix DBM; Bonus CC Matrix; Bonus II DMB; Cellentra Advanced Allograft; EquivaBone; FiberStack DBM; Fortis ALIF, Composite, Cortical, PLIF, TLIF; Indux Cortical or Cancellous; InterGro DBM; PrimaGen Advanced Allograft; Osteostim Composite; Cortical, ALIF, PLIF; StaGraft Cancellous; StaGraft DBM; StaGraft Fiber; Trinnect

Proprietary Name(s): Skin HuMend; DermaSpan; DermaSpan Mesh
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.

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, 2019
Expiration Date: June 29, 2020

Robert J. Thomas
Robert J. Thomas, Acting Branch Chief
Laboratory Field Services
STATE OF CONNECTICUT
DEPARTMENT OF CONSUMER PROTECTION

This is your registration certificate for your records. Such registration shall be shown to any properly interested person on request. Do not attempt to make any changes or alter this certificate in any way. This registration is not transferable. Questions regarding this registration can be emailed to the Drug Control Division at dcp.drugwholesalers@ct.gov.

In an effort to be more efficient and Go Green, the department asks that you keep your email information current. The email on your account will be used for all correspondence from this office.

You can update your address and email address or print a duplicate certificate by logging into your account with your User Id and Password at www.elicense.ct.gov. If you need your User Id and/or Password, please email dcp.online@ct.gov.

Mailing address:
MILLSTONE MEDICAL OUTSOURCING LLC
8836 POLK LN STE 100
OLIVE BRANCH, MS  38654-7812

Email on file to be used for receiving all notices from this office:
vhughes@millstonemedical.com

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:  07/01/2019
Expiration Date:  06/30/2020

verifly online at www.elicense.ct.gov

Michelle Seagull, Commissioner
Monday, March 18, 2019
Kimyotta Fernanders
Millstone Medical Outsourcing, LLC
Olive Branch, MS 38654

Dear Kimyotta Fernanders,

This letter confirms that Millstone Medical Outsourcing, LLC is registered with the Delaware Tissue Bank until April 30, 2020.

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 the Bureau at 302-744-1050.

Best regards,

Delaware Division of Public Health
Bureau of Communicable Diseases
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: 10/28/2018
EXPIRATION DATE: 10/27/2020

Deputy Secretary, Division of Health Quality Assurance
Millstone Medical Outsourcing, LLC

Dear Director:

We are in receipt of your 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,

[Signature]

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.
DISTRIBUTOR OF LEGEND DRUGS OR LEGEND DEVICES
SUB-TYPE: Third-Party Logistic Provider Distributor

MILLSTONE MEDICAL OUTSOURCING, LLC

License No. 7477 effective 01/01/2019 (Original issue date: 01/02/2013), Expiring 12/31/2019

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 1986 (as amended).

This license is subject to regulation in the state of Louisiana

in accordance with La. R.S. 37:3481 through 3482 and LAC 46-XXXIV.101 through 1503.

Additional Third-Party Logistics Providers:

NA

Board Secretary

This License is NOT TRANSFERABLE and must be conspicuously displayed. This license must be renewed annually.

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, repackers, 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, repackers, 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, homoeopathic 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

Patsingshaw, May 2023
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
Musculoskeletal tissue

Tissue Storage Facility
Musculoskeletal tissue
Amniotic membrane

Issued: February 19, 2016
Expires: March 1, 2020

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

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

DOH-3908 (04/2001)
January 14, 2019

Ms. Kimyotta Fernanders  
Millstone Medical Outsourcing, LLC  
8836 Polk Lane, Suite 100  
Olive Branch, MS  38654

Dear Ms. Fernanders:

This letter is to notify you that Millstone Medical Outsourcing, LLC has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on January 26, 2022.

Thank you for your patience in processing your renewal. Should you have any questions, please call (971) 673-0540 or email to mailbox.hclc@state.or.us.

Sincerely,

[Signature]
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
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: 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)
   
   FEB: 3008769422

2. REASON FOR SUBMISSION
   a. INITIAL REGISTRATION / LISTING
   b. X ANNUAL REGISTRATION / LISTING
   c. CHANGE IN INFORMATION
   d. INACTIVE

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 Biologies, LLC
   2800 Roosevelt Street
   Carlsbad, California 92008
   a. PHONE 800-272-0267
      b. SATCHEL RECOVERY ESTABLISHMENT
      c. MANUFACTURING ESTABLISHMENT FEI NO.
      d. TESTING FOR MICRO-ORGANISMS ONLY

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 Biologies, LLC
   Attn: Jesse Adawag
   2800 Roosevelt Street
   Carlsbad, California 92008
   a. PHONE 800-272-0267
      b. PHONE

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

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

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps
   Types of HCT / Ps
   Recover Screen Test Package Process Store Label Distribute
   a. Bone X X X
   b. Cartilage
   c. Cornea
   d. Dura Mater
   e. Embryo
      SIP
      Directed
      Anonymous
   f. Fascia
   g. Heart Valve
   h. Ligament
   i. Coccygeal
      SIP
      Directed
      Anonymous
   j. Pericardium
   k. Peripheral
      Blood Stem
      Autologous
      Family Related
   l. Solera
   m. Semen
      SIP
      Directed
      Anonymous
   n. Skin
   o. Somatic Cell
      Therapy Products
      Autologous
      Family Related
      Allogeneic
   p. Tendon
   q. Umbilical
      Cord Blood
      Autologous
      Family Related
   r. Vascular Graft
   s.
   t.
   u.
   v.

14. PROPRIETARY NAME(S)
   OsteoAMP

FORM FDA - 3556 (7/17)
### ADDITIONAL INFORMATION:

Annual registration renewal for FEI: 3008769422.
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)

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.

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
1905 ASTON AVE, STE 101
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, 2019
Expiration Date: June 22, 2020

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services
Tuesday, March 26, 2019

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, 2020.

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 the Bureau at 302-744-1050.

Best regards,

Delaware Division of Public Health
Bureau of Communicable Diseases
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

Deputy Secretary, Division of Health Quality Assurance
Effective Date: May 01, 2019
Expires: May 01, 2020

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

Registration Number 2214

State of Illinois
2019
Sperm And Tissue
Establishment Registration

Advanced Biologics, LLC

Dear Director:

We are in receipt of your 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,

[Signature]

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
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

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
Expires: April 1, 2020

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

Property of the New York State Department of Health. Valid only at the address shown. Must be conspicuously posted.
January 27, 2017

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,

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 29th day of July 2017

[Seal]

Chairman

President & Chief Executive Officer

Accreditation # 000359 (Revised)
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 loverdi@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,

Frank S. Wilton  
President & Chief Executive Officer

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

Jason E. LoVerdi, MHA, CTBS
Accreditation Manager
### PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
   - a. BLOOD FDA 2830
   - b. DEVICES FDA 2891
   - c. DRUG FDA 2656

4. PHYSICAL LOCATION
   (Include legal name, number and street, city, state, country, and post office code)
   Community Blood Center dba Community Tissue Services
   349 S. Main Street
   Dayton, Ohio  45402-2715

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)
   Community Blood Center dba Community Tissue Services
   Attn: David M. Smith, MD
   349 S. Main Street
   Dayton, Ohio  45402-2715

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT
   a. PHONE 937-461-3450
   b. PHONE

9. REPORTING OFFICIAL’S SIGNATURE
   a. TYPED NAME  David M. Smith, MD
   b. E-MAIL  pmalone@cbccts.org
   c. TITLE  CEO

### PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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<tr>
<th>Types of HCT / Ps</th>
<th>Establishment Functions</th>
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<td>Recover</td>
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<td>a. Bone</td>
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<td>b. Cartilage</td>
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<td>c. Cornea</td>
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<td>g. Heart Valve</td>
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<td>h. Ligament</td>
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<td>Cord Blood</td>
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<tr>
<td>r. Vascular Graft</td>
<td>X</td>
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<td>s.</td>
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<td>u.</td>
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<tr>
<td>v.</td>
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</tbody>
</table>

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)
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.

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, 2019
Expiration Date: June 23, 2020

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services
Thursday, January 03, 2019
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, 2020.

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 call 302-744-1050.

Best regards,

Delaware Division of Public Health
Bureau of Communicable Diseases
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

EFFECTIVE DATE: 11/03/2018
EXPIRATION DATE: 11/02/2020

Deputy Secretary, Division of Health Quality Assurance
Effective Date: May 01, 2019
Expires: May 01, 2020

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
2019
Sperm And Tissue Establishment Registration

Community Blood Center D/B/A Community Tissue Services

Dear Director:

We are in receipt of your 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,

[Signature]
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
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

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
Expires: September 1, 2021

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

Owner: Community Blood Center

DOH-3908 (04/2001)
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,

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

[Seal]

Chairman

President & Chief Executive Officer

Accreditation # #00088/8
<table>
<thead>
<tr>
<th>HCT/P(s)</th>
<th>Donor Type(s)</th>
<th>Establishment functions</th>
<th>Date of Discontinuance</th>
<th>Date of Resumption</th>
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<td>Peritoneal Membrane</td>
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<td>Sclera</td>
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<td>Semen</td>
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<td>Umbilical Cord Tissue</td>
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</tbody>
</table>

**FEI:** 1000307504

**Reporting Official:**
Carrie S Crocker, Sr. Director, GTP Quality Systems
1714 Hayes Street
Nashville, Tennessee 37203
USA
Phone: 615-564-3774 Ext.
carrie.crocker@doits.org

**Legal Name:**
DCI Donor Services Tissue Bank

**Reason For Last Submission:**
Annual Registration/Listing

**Last Annual Registration Year:**
2019

**Last Registration Receipt Date:**
11/16/2018

**Summary Report Print Date:**
12/19/2018

**Satellite Recovery Establishment:**
No

**Parent Manufacturing Establishment FEI No.:**
No

**Testing For Micro-Organisms Only:**
No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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.

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 operations 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, 2019
Expiration Date: September 3, 2020

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.

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, 2019
Expiration Date: September 3, 2020

[Signature]
Robert J. Thomas, Acting Branch Chief
Laboratory Field Services
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

Deputy Secretary, Division of Health Quality Assurance
November 7, 2017

Administrator
DCI Donor Services
1714 Hayes Street
Nashville, TN  37203

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
OFFICE OF HEALTH CARE QUALITY
LABORATORIES AND TISSUE BANKS
55 WADE AVE BLAND BRYANT BLDG
CATONSVILLE, MD 21228-4663

TISSUE BANK PERMIT
NON - EXPIRING

NUMBER: TB1640     EFFECTIVE DATE: 07/01/2018

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: 74703

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.

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
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 (04/2001)
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,

[Signature]

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
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: 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

Chairman

President & Chief Executive Officer

Accreditation # 00039/9
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,

Jason E. LoVerdi, MHA, CTBS
Vice President of Accreditation
## PART I - ESTABLISHMENT INFORMATION

### 3. OTHER FDA REGISTRATIONS

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<th>FDA Registration Type</th>
<th>No.</th>
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<td>Devices FDA 2891</td>
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<td>Drug FDA 2656</td>
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### 4. PHYSICAL LOCATION

Lifelink of Georgia (Atlanta Office)

2875 Northwoods Pkwy
Norcross, Georgia 30071

<table>
<thead>
<tr>
<th>PHONE</th>
<th>800-544-6667</th>
<th>EXT</th>
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<td>PHONE</td>
<td>800-544-6667</td>
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## PART II - PRODUCT INFORMATION

### 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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### 11. HCT/Ps DESCRIBED IN 21 CFR 1271.10

- a. Bone
- b. Cartilage
- c. Cornea
- d. Dura Mater
- e. Embryo
- f. Fascia
- g. Heart Valve
- h. Ligament
- i. Oocyte
- j. Pericardium
- k. Peripheral Blood stem
- l. Sclera
- m. Semen
- n. Skin
- o. Somatic Cell Therapy Products
- p. Tendon
- q. Umbilical Cord Blood
- r. Vascular Graft

### 12. HCT/Ps REGULATED AS MEDICAL DEVICES

### 13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS

### 14. PROPRIETARY NAME(S)

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## Part I - Establishment Information

### 3. Other FDA Registrations
- a. Blood FDA 2830
- b. Devices FDA 2891
- c. Drug FDA 2656

### 4. Physical Location
Include legal name, number and street, city, state, country, and postal office code.

- LifeLink Tissue Bank - Orlando
  1743 South Orange Ave.
  Orlando, Florida 32806

### 5. Enter Corrections to Item 4

### 6. Mailing Address of Reporting Official
Include institution name if applicable, number and street, city, state, country, and postal office code.

- LifeLink Tissue Bank
- Attn: Elizabeth S. Horn-Brinson, BS
- 9661 Delaney Creek Boulevard
- Tampa, Florida 33619

### 7. Enter Corrections to Item 6

### 8. U.S. Agent

- a. E-mail
- b. Phone

### 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

## Part II - Product Information

### 10. Establishment Functions and Types of HCT / Ps

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Legal Name and Location:
LifeLink Foundation, Inc. d/b/a LifeLink Tissue Bank
9661 Delaney Creek Boulevard
Tampa, Florida 33619
USA
Phone: 813-886-8111 Ext: 4324

FEI: 3008286876

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:

Satellite Recovery Establishment:

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

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Reason For Last Submission: Change in Information
Last Annual Registration Year: 2019
Last Registration Receipt Date: 12/19/2018
Summary Report Print Date: 01/28/2019

FEI: 3008286876

Drug: Other FDA Registrations: Blood: Devices: FEI: 3008286876

FEI: 3008286876

Legal Name: LifeLink Foundation, Inc. d/b/a LifeLink Tissue Bank

FDA information collection OMB Control number: 0910-0543, expiration date: 6/30/2020

Page 1 of 2
Additional Information: LifeLink of Florida OPO formerly FEI#:3003453640 is also located at this location and has been consolidated into FEI#:3008286876, LifeLink Foundation, Inc. d/b/a LifeLink Tissue Bank, Delaney Creek.

Proprietary Names for Bone: AlloPure, Allosculpt, Hero, Indux, LifeFlex, LifeGraft, NuFix, Optecure, OsteoAmp, Osteocel Plus, Osteocel Pro, Osteostim, Primagraft, Purebone, SiJoin, Vikos, Vesuvius, SiFix

Proprietary Name(s):
# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## 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)

---

### PART I - ESTABLISHMENT INFORMATION

#### 3. OTHER FDA REGISTRATIONS

- a. BLOOD FDA 2830
- b. DEVICES FDA 2891
- c. DRUG FDA 2656

#### 4. PHYSICAL LOCATION

Include legal name, number and street, city, state, country, and post office code

- Daimler-Chrysler Bldg./Metro Office Park
  1 Calle 1, Suite 100
  Guaynabo, Puerto Rico 00968-1711

- LifeLink of Puerto Rico
  Attn: Elizabeth S. Horn-Brinson
  9661 Delaney Creek Boulevard
  Tampa, Florida 33619

- a. PHONE 800-558-0977
  - EXT
- b. SATELLITE RECOVERY ESTABLISHMENT
  - MANUFACTURING ESTABLISHMENT FEI NO.
- c. TESTING FOR MICRO-ORGANISMS ONLY

#### 5. ENTER CORRECTIONS TO ITEM 4

---

### PART II - PRODUCT INFORMATION

#### 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

<table>
<thead>
<tr>
<th>Types of HCT / Ps</th>
<th>Establishment Functions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recover</td>
</tr>
<tr>
<td>a. Bone</td>
<td>X</td>
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<tr>
<td>b. Cartilage</td>
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<tr>
<td>c. Cornea</td>
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<tr>
<td>d. Dura Mater</td>
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<tr>
<td>e. Embryo</td>
<td>SIP</td>
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<tr>
<td>f. Fascia</td>
<td>X</td>
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<tr>
<td>g. Heart Valve</td>
<td>X</td>
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<tr>
<td>h. Ligament</td>
<td>X</td>
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<tr>
<td>i. Oocyte</td>
<td>SIP</td>
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<tr>
<td>j. Pericardium</td>
<td>X</td>
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<tr>
<td>k. Peripheral</td>
<td>Autologous</td>
</tr>
<tr>
<td>Blood Stem</td>
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<tr>
<td>l. Sclera</td>
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<td>m. Semen</td>
<td>SIP</td>
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<td>n. Skin</td>
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<td>o. Somatic Cell</td>
<td>Autologous</td>
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<td>Therapy Products</td>
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<td>p. Tendon</td>
<td>X</td>
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<tr>
<td>q. Umbilical</td>
<td>Autologous</td>
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<tr>
<td>Cord Blood</td>
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<tr>
<td>r. Vascular Graft</td>
<td>X</td>
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</tbody>
</table>

#### 11. HCT/Ps DESCRIBED IN 21 CFR 1271.10

- a. INITIAL REGISTRATION / LISTING
- b. ANNUAL REGISTRATION / LISTING
- c. CHANGE IN INFORMATION
- d. INACTIVE

#### 12. HCT/Ps REGULATED AS MEDICAL DEVICES

#### 13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS

#### 14. PROPRIETARY NAME(S)

---

### 8. U.S. AGENT

- a. PHONE 813-804-4325
  - EXT 4325

---

### 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, 2018
Expiration Date: December 28, 2019

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services
Tuesday, February 12, 2019

Terra R. B. Bootle  
LifeLink Tissue Bank  
Tampa, FL 33619  

Dear Terra R. B. Bootle,  

This letter confirms that LifeLink Tissue Bank is registered with the Delaware Tissue Bank until April 30, 2020.

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 the Bureau at 302-744-1050.

Best regards,

Delaware Division of Public Health  
Bureau of Communicable Diseases
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
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

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 - 05/30/2020

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

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:
Daniel L. Schultz, M.D.

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

Issued: May 10, 2019
Expires: June 1, 2021

Owner: LifeLink Foundation

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

[Signature]
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
September 27, 2018

Pinnacle Transplant Technologies, LLC
Attn: Mr. Gabriel Hyams, President
125 W. Pinnacle Peak Rd, Bldg. 2
Phoenix, AZ 85027

Dear Mr. Hyams:

On behalf of the Board of Governors, I am pleased to inform you that the American Association of Tissue Banks (AATB) has approved Pinnacle Transplant Technologies, LLC for accreditation after you had successfully addressed the nonconformities resulting from the inspection. The accreditation covers Donor Eligibility Assessment, Processing, Release, Storage and Distribution of Musculoskeletal, Skin and Birth 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 January 17, 2021. 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. 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,

Frank S. Wilton
President & Chief Executive Officer

Accreditation # 00201/3; Accreditation Date: September 27, 2018

Attached: Certificate
American Association of Tissue Banks

Herewith certifies
that the Institution named here

Pinnacle Transplant Technologies, LLC
Phoenix, Arizona

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

September 27, 2018 – January 17, 2021

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 27th day of September 2018

[Seal]

Chairman

President & Chief Executive Officer

Accreditation # 00201/3
**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)*

**PART I - ESTABLISHMENT INFORMATION**

3. OTHER FDA REGISTRATIONS
   - a. BLOOD FDA 2830
     - NO.__________________________
   - b. DEVICES FDA 2891
     - NO. FEI: 3008927553
   - c. DRUG FDA 2656
     - NO.__________________________

4. PHYSICAL LOCATION
   (Include legal name, number and street, city, state, country, and post office code)
   Pinnacle Transplant Technologies, LLC
   1125 W. Pinnacle Peak Rd
   Bldg 2
   Phoenix, Arizona 85027
   - a. PHONE 623-277-5400  EXT 405
   - b. SATELITE RECOVERY ESTABLISHMENT MANUFACTURING ESTABLISHMENT FEI NO.
   - c. TESTING FOR MICRO-ORGANISMS ONLY

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)
   Pinnacle Transplant Technologies, LLC
   Attn: Danielle Rose R. Cox, BS, CQA
   1125 W. Pinnacle Peak Rd
   Bldg 2
   Phoenix, Arizona 85027
   - a. PHONE 623-277-5400  EXT 441

7. ENTER CORRECTIONS TO ITEM 6
   b. PHONE

8. U.S. AGENT
   a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE
   - a. TYPED NAME Danielle Rose R. Cox, BS, CQA
   - b. E-MAIL dcox@pinnacletransplant.com
   - c. TITLE Regulatory Affairs Specialist
   - d. DATE 09-JAN-2018

**PART II - PRODUCT INFORMATION**

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps


<table>
<thead>
<tr>
<th>Types of HCT / Ps</th>
<th>Establishment Functions</th>
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<td>Recover</td>
<td>Screen</td>
<td>Test</td>
<td>Package</td>
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<td>d. Dura Mater</td>
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14. PROPRIETARY NAME(S)

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*** See full text on next page
**ADDITIONAL INFORMATION:**

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<tr>
<th>Proprietary Name(s):</th>
<th></th>
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<tbody>
<tr>
<td>a. Bone</td>
<td>Apex DBM Putty, Apex DBM Crunch, Apex DBM Fiber, Apex FP, Apex FP Plus, Ossif-isem (tm)</td>
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<td>Amniotic Membrane</td>
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<td>Amnio Biologix, AmnioFlex, SX Fluid, SX Matrix, Palingen Flow, Palingen SportFlow, Promatrix ACF, KardiaFlow, Nanofactor,</td>
</tr>
</tbody>
</table>
### Legal Name and Location:
Pinnacle Transplant Technologies, LLC  
1125 W. Pinnacle Peak Rd  
Bldg 1 and 2  
Phoenix, Arizona 85027  
USA

Phone: 623-277-5400  
Ext.: 405

### Reporting Official:
Danielle Rose T Cox, Regulatory Affairs Specialist  
1125 W. Pinnacle Peak Rd  
Bldg 1  
Phoenix, Arizona 85027  
USA

Phone: 623-277-5400  
Ext. 441  
dcox@pinnacletransplant.com

### Establishment Functions

<table>
<thead>
<tr>
<th>HCT/P(s)</th>
<th>Donor Type(s)</th>
<th>Recover</th>
<th>Screen</th>
<th>Donor Testing</th>
<th>Package</th>
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### Additional Information:

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<th>Product Type</th>
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<td>Amniotic Membrane</td>
<td>(Continuation) SulGen Membrane, SulGen Hydromembrane, Stratogen Plus Membrane, Stratogen Membrane, PalinGen XPlus Membrane</td>
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<td>Palingen Membrane, Palingen Hydromembrane, Palingen XPlus Hydromembrane, Kardia Membrane, SX Barrier, ASGBarrier</td>
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<td>Bone</td>
<td>Apex DBM Putty, Apex DBM Crunch, Apex DBM Fiber, Apex FP, Apex FP Plus, Ossif-isem (tm)</td>
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</table>

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FEI: 3008927553

**Legal Name:** Pinnacle Transplant Technologies, LLC

FDA information collection OMB Control number: 0910-0543, expiration date: 6/30/2020
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)

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.

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services
Dear Danielle Cox,

This letter confirms that Pinnacle Transplant Technologies, LLC is registered with the Delaware Tissue Bank until April 30, 2020.

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 the Bureau at 302-744-1050.

Best regards,

Delaware Division of Public Health
Bureau of Communicable Diseases
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

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

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
Medical Director: Dennis L. Furr, M.D.
President/Executive Director

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
Expires: April 1, 2021

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

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

DOH:3908 (04/2001)
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
Expires: April 1, 2021

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

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

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
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: 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]