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

P 800.637.4391
F 888.279.0152
www.BioventusSurgical.com

Table of Certification

Bioventus LLC

Distributor: Millstone Medical Outsourcing

Instructions For Use

510(k) Clearance Letters

Tissue Banks

Xtant Medical

bioventus® SURGICAL

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

P 800.637.4391
F 888.279.0152
www.BioventusSurgical.com

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

17 June 2016
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 DESCRIBED IN 21 CFR 1271.10

FEI: 3007499718

Other FDA Registrations:
Blood:
Devices: FEI: 3010097171
Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022
Last Registration Receipt Date: 11/16/2021
Summary Report Print Date: 12/01/2021

Legal Name and Location:

Millstone Medical Outsourcing
8836 Polk Lane
Suite 100

Olive Branch, Mississippi 38654
USA

Phone: 508-679-8384 **Ext.:**

Reporting Official:

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

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI 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)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane							X	X	X			***See full text on next page.
Blood Vessel												
Bone							X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							X	X	X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X	X	X			***See full text on next page.
Tendon							X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue							X	X	X			***See full text on next page.

FDA information collection OMB Control number: 0910-0543, expiration date: 07/31/2023

Additional Information: No additional information provided.

Proprietary Name(s):		
	Amniotic Membrane	BioFix; Amniofix; CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; Amnioflo; Flower AmnioPatch; FlowerPatch; AMNIOGRAFT; AMNIOGUARD; CLARIX 100; CLARIX CORD; CLARIX FLO; NEOX 100; NEOX CORD; NEOX FLO; NEOX RT; TAG- Triple Layer Amniotic Graft
	Bone	Osteoamp; Purebone; Exponent; Allograft Bone Wedge; SeaSpine Capistrano Cervical Spacer; SeaSpine PLIF Allograft; SeaSpine Compressible Bone Matrix; SeaSpine Cervical Allograft; Laminoplasty Cortical Allograft; LESBiologics; DBMForm; FacetFuse; Allo-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; Puros; Puros-S; Fortitude; Bonus Triad; Copios; FIBERFORM; FIBER BOAT; FIBER ANCHOR; FIBER BULLETS; FIBERFORM+; FIBERFORM SYRINGE; FIBERFORM, OSTEOAMP SELECT Flowable, FlowerGRAFT; FibreX Demineralized Bone Fibers; Bigfoot; BioAdapt; BioReady; BioSet; Elemax
	Skin	HuMend; DermaSpan; DermaSpan Mesh; FlowerDerm
	Umbilical Cord Tissue	CTM Thin; CTM Thick; CTM Flow; CTM Boost; CTM Paste; CTM Powder; CTM Flow LV

FEI: 3007499718

Legal Name: Millstone Medical Outsourcing

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: June 30, 2021
Expiration Date: June 29, 2022

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services

CPL-03 Rev 06/13

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 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 with our office current to receive correspondence. All renewal notifications and certificates will only be emailed to your last reported email on record. You can update your email, mailing address or print a duplicate certificate by logging into your account with your User ID and Password at www.elicense.ct.gov. Visit our website at www.ct.gov/dcp.

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

812700

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

WHOLESALER OF DRUGS, COSMETICS & MEDICAL DEVICES

Controlled Substances: No **Rx Legend Drugs: No** **Non Rx Legend Drugs: Yes** **Medical Devices: Yes**

Cosmetics: No **Medical Gases and Oxygen: No** **Durable Medical Equipment (DME): Yes**

Registration #: CSW.0002406
Effective Date: 07/01/2021
Expiration Date: 06/30/2022

verify online at www.elicense.ct.gov

Michelle Seagull, Commissioner

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

April 5, 2021

Kimyotta Martin
Millstone Medical Outsourcing
8836 Polk Lane, Suite 100
Olive Branch, MS 38654

Dear Kimyotta Martin,

This letter confirms that **Millstone Medical Outsourcing** is registered with the Delaware Tissue Bank until April 30, 2022.

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,

Diane Smith

Diane Smith
Compliance Specialist
Delaware Division of Public Health
Bureau of Infectious Disease Prevention & Control
Ph. 302-744-1226 Fax 302-739-2550
DHSS_DPH_tissuebank@delaware.gov

View current license information at: Floridahealthfinder.gov

LICENSE #: 166
CERTIFICATE #: 1723

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 rules and regulations adopted by the State of Florida, Agency for Health Care Administration, and authorized in Chapter 765, Florida Statutes, and is authorized to operate the following:

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

Authorized Services: distribute tissues

EFFECTIVE DATE: 01/26/2021

EXPIRATION DATE: 01/25/2023

Simone Marstiller, Secretary
Division of Health Quality Assurance

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

March 24, 2021

Email: Kimyotta.Martin@Millstonemedical.Com

Kimyotta Martin, Agency Director
Millstone Medical Outsourcing LLC
8836 Polk Lane Ste 100
Olive Branch, MS 38654

File Number: 41950219
License Number: 166
Provider Type: Organ and Tissue Procurement

RE: Facility locator at 8836 Polk Lane Ste 100, Olive Branch

Dear Administrator:

The enclosed Organ and Tissue Procurement license with license number 166 and certificate number 1723 is issued for the above provider effective January 26, 2021 through January 25, 2023. The license is being issued for approval of the change during licensure period 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 and In-Home Services 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 - 4372 or by email at Dana.Hines@ahca.myflorida.com.

Sincerely,

Dana Hines

Laboratory and In-Home Services Unit
Division of Health Quality Assurance

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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

Effective Date: **May 01, 2021**

Expires: May 01, **2022**

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

Registration Number 0110

State of Illinois
2021
Sperm/Tissue Bank Registration

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 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,

Brandon Rakowski
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.

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 **01/01/2022** *(Original issue date: 01/02/2013)*, Expiring **12/31/2022**
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.drugboard.la.gov Email: admin@drugboard.la.gov

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
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: TB1858 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:

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, Epididmyal Aspirates, Ovarian Tissue, Preimplantation Genetic Testing, Reproductive Tissue, Sperm, Testicular Tissue

CONTROL: **74813**

Patricia Tomasko May, MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the impostition 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.: 1607

Tissue Bank Director:
Michael Scott Jones
Director of Quality

Medical Director:
Michael B. Bagwell, D.O.

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: April 17, 2020

Expires: May 1, 2022

Owner: Millstone Medical Outsourcing, 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)

Oregon Health Authority

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

January 26, 2022

Michael Scott Jones
Millstone Medical Outsourcing, LLC
8836 Polk Lane, Suite 100
Olive Branch, MS 38654

Dear Mr. Jones:

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, 2025.

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

Sincerely,

John Adams
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 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: 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]

DCI Donor Services Tissue Bank
an extraordinary commitment to science, health and hope

REFICIO DEMINERALIZED BONE MATRIX (DBM) PUTTY PACKAGE INSERT

STERILE R

READ BEFORE USING

DESCRIPTION

This bone void filler was prepared from donated human tissue processed using aseptic surgical techniques. Reficio DBM Putty is a combination of human demineralized bone matrix (DBM) and a biocompatible and bioabsorbable carrier, carboxymethylcellulose, mixed into a putty-like consistency for ease of surgical use. Reficio DBM Putty is processed using either fine particles of bone or a mixture of fine particles and larger granules.

Tissue is first disinfected and then terminally sterilized in the final package using low-dose gamma radiation to provide a SAL of 10^{-6}. The material may contain traces of the processing reagents Gentamicin, PVP-Iodine, alcohol and surfactants, hydrochloric acid and phosphate buffer. As a biological material, some variations in the product should be expected, such as in appearance and in handling.

OSTEOINDUCTIVITY POTENTIAL

Reficio DBM Putty is osteoconductive and has been shown to have osteoinductive potential in an athymic rat model. It is manufactured via a processing method that has been validated to consistently produce DBM that is osteoinductive in an athymic rat assay. Product and process consistency are confirmed via ongoing testing of DBM Putty finished product for osteoinductivity in a validated athymic rat assay. It is unknown how the osteoinductivity potential in the rat model correlates with human clinical performance.

DONOR SCREENING AND TESTING

The donor from whom this allograft was derived has been tested and found negative for the following:

HBsAg (Hepatitis B Surface Antigen), HBcAb (Hepatitis B Core Total Antibody), HBV-NAT (Hepatitis B Nucleic Acid Test), HCV (Hepatitis C Antibody), HIV 1/2-Ab (Antibody to Human Immunodeficiency Virus Types 1 and 2), Syphilis detection test, HIV-1 NAT (HIV-1 Nucleic Acid Test), and HCV NAT (HCV Nucleic Acid Test).

The donor was also tested for HTLV I/II (Human T lymphotrophic Virus Types I and II) and the results were found to be acceptable. Note: HTLV I/II testing is not currently a required test. If a donor was NOT tested for HTLV I/II the donor will be statused as a USA-only donor.

Additional RCDAD Donor Screening Tests Attached in this Space.

If additional donor screening tests for RCDADs are not listed in this space there were none performed.

Additional donor screening tests may have been performed on the donor. If additional tests for Human Immunodeficiency Virus, Hepatitis C or Syphilis were performed the results were reviewed and found to be **NEGATIVE**. Additional tests for other communicable diseases, such as West Nile Virus, *T. Cruzi*, Cytomegalovirus and Epstein Barr Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according to regulations, standards and Xtant Medical policies and procedures.

If additional screening tests were performed for relevant communicable disease agents and diseases (RCDADs) as defined by the US FDA, they will be listed along with results in the box labeled “Additional RCDAD Donor Screening Tests Attached In This Space”. Donor screening tests are performed by laboratories registered with FDA to perform donor testing using FDA-licensed tests, when available, and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493.

The donor was selected based on results of the donor screening tests, review of the donor’s medical history, social history, external exam and relevant medical records available at the time of recovery which may include previous medical history, laboratory test results, autopsy and coroner reports (if performed), and information obtained from any source or records which may pertain to donor eligibility. Such records have been evaluated by Xtant Medical’s Medical Director and are sufficient to indicate that donor eligibility criteria in place at the time of procurement have been met. This tissue is eligible for transplantation.

The names and addresses of the testing laboratories, the listing and interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records, and the name of the person or establishment determining the eligibility of this human tissue are on file at Xtant Medical and are available upon request. The criteria used for donor selection are in accordance with current policies and procedures approved by Xtant Medical. Policies and procedures for donor screening, serologic and microbiologic testing meet current standards established by the American Association of Tissue Banks and FDA Federal Regulations and Guidance Documents.

INDICATIONS AND USAGE

Reficio DBM Putty is indicated for use as a bone void filler and bone graft substitute for voids or gaps that are not intrinsic to the stability of the bony structure. Reficio DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.

Reficio DBM Putty can be used as follows:

- Extremities
- Posterolateral spine
- Pelvis

A US flag on the packaging of the graft indicates the graft is only approved for distribution and use in the United States of America.

CONTRAINDICATIONS / PRECAUTIONS

The allograft should not be used if the expiration date has been surpassed, the container in which the product is stored is damaged, the product is not labeled, or the required storage conditions have not been maintained. Caution should be exercised if the patient is allergic to any of the antibiotics or chemicals listed in processing and testing. The presence of infection at the transplantation site is a contraindication for the use of this allograft.

Reficio DBM Putty is contraindicated where the device is intended for structural support in load-bearing bone and in articulating surfaces. Relative contraindications include the following

- Severe vascular or neurological disease
- Fever
- Uncontrolled diabetes
- Severe degenerative bone disease

- Pregnancy
- Hypercalcemia
- Renal impairment
- Active or latent infection
- History of, or active Pott's disease
- Osteomyelitis or sepsis at the surgical site
- Inability to co-operate or comprehend post-operative instructions

ADVERSE EFFECTS

Possible adverse effects of using Reficio DBM Putty include, but are not limited to:

- Infection of soft tissue and/or bone (osteomyelitis)
- Fever
- Deformity of the bone at the site
- Incomplete bone ingrowth, delayed union or non-union
- Hypercalcemia or transient hypercalcemia
- Fracture of the newly formed bone
- Disease transmission and undesirable immune response. Extensive screening procedures have been used in the selection of tissue donors. In spite of this careful donor selection and serological testing, transmission of infectious diseases such as HIV or hepatitis could occur.

Any Transmission Of Disease That Is Suspected To Be Caused By Reficio DBM Putty Or Any Other Adverse Outcome Potentially Attributed To This Graft Must Be Reported Promptly To DCI Donor Services Tissue Bank.

INSTRUCTIONS FOR USE

Caution: Reficio DBM Putty Is Provided Sterile. DO NOT RESTERILIZE.

1. Reficio DBM Putty packaging consists of the following: a) Outer Pouch (non-sterile); b) Inner Foil Pouch (sterile); and c) Sealed Jar or Capped Syringe (sterile).
2. Examine the outer pouch for integrity. Do not use if there is evidence that the outer pouch is damaged or sterility has been compromised, or if the product label or identifying bar code is severely damaged, illegible or missing. Confirm that the expiration date shown on the label has not passed.
3. Peel open the outer pouch using aseptic technique.
4. Introduce the sterile contents onto the sterile field.
5. Remove the sealed jar or capped syringe and twist off jar lid or syringe cap.
6. Remove putty or push on plunger to extrude putty for use.
7. Apply and use the Reficio DBM Putty as per established surgical technique and surgeon's preference.

Caution: This Allograft Material Is Intended For Single-Patient Use, On A Single Occasion Only. Discard Any Unused Material After The Package Has Been Opened.

Caution: Human tissue for transplantation shall not be offered, distributed or dispensed for veterinarian use.

VIRAL INACTIVATION AND CLEARANCE

The process used to make Demineralized Bone Matrix for Reficio DBM Putty was validated for its ability to inactivate and/or clear a panel of model human enveloped and non-enveloped viruses representing DNA- and RNA-containing viruses and various viral shapes and sizes. This testing demonstrated the process provides suitable viral inactivation potential for a wide spectrum of potential human viruses. This inactivation potential provides additional viral contamination risk reduction beyond that provided through donor screening.

TISSUE TRACKING

Reficio DBM Putty is packaged in sterile, single-patient-use containers and the Unique Graft Serial Number, expiration date, product code, size, and additional information are listed on the package label.

Extra labels have been included with this graft for use by the end-user.

The Hospital must maintain records so that possible infections or other adverse reactions associated with this product can be linked back to the original source. It is the responsibility of the user surgeon to complete recipient records for the purpose of tracking tissue post-transplant.

STORAGE

It is the responsibility of the Tissue Dispensing Service and/or end-user clinician or facility to maintain this product in appropriate storage conditions prior to transplantation.

Reficio DBM Putty - Store at 15°C to 30°C. Do not freeze or expose to extreme heat.

RETURNS

If for any reason tissue must be returned, please contact the Customer Service department at DCI Donor Services Tissue Bank for return instructions.

Caution: Federal (US) Law Restricts This Device To Sale, Distribution And Use By Or On The Order Of A Physician.

Donor Assessment and Tissue Processed by:
Xtant Medical
664 Cruiser Lane
Belgrade, MT 59714
888-886-9354

Distributed by:
DCI Donor Services Tissue Bank
566 Mainstream Dr., Suite 300
Nashville, TN 37228
Phone: 800-216-0319
Fax: 615-327-2381
tissuebank.dcids.org

510(k) SUMMARY
(Per 21 CFR 807.92)

MAY 3 1 2013

General Company Information

Name: Bacterin International, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

Address: Bacterin International, Inc.
600 Cruiser Lane
Belgrade, MT 59714

Telephone: (406) 388-0480
Fax: (406) 683-9476

Date Prepared May 30, 2013

General Device Information

Product Name: OsteoSelect® Demineralized Bone Matrix Putty
Common Name: Bone Void Filler

Classification: Resorbable calcium salt bone void filler device
21 CFR 888.3045 - Product code: MBP, MQV

Class II

Predicate Devices

OsteoSelect® Demineralized Bone Matrix Putty
Bacterin International, Inc.
510(k) K091321 (use in extremities and pelvis)

DBX® Demineralized Bone Matrix Putty
Musculoskeletal Transplant Foundation
K103784 (use in pelvis and extremities)
K103795 (use in posterolateral spine)

Description

OsteoSelect® DBM Putty is processed human bone that has been demineralized and combined with an absorbable carrier that is biocompatible and biodegradable. The combination of demineralized bone and the absorbable carrier results in a putty-like consistency for ease and flexibility of use during surgical application. The carrier material is a mixture of carboxymethylcellulose (a wax-like material) and phosphate buffered saline (a dispersing agent). OsteoSelect® DBM Putty is virtually odorless, tan in color and can be spread easily with minimal adhesion to surgical gloves.

OsteoSelect® DBM Putty is intended for use as a filler for voids or gaps that are not intrinsic to the stability of the bony structure. The putty will be absorbed within a period of 90 days.

Intended Use (Indications)

OsteoSelect® DBM Putty is indicated for use as a bone void filler and bone graft substitute for voids or gaps that are not intrinsic to the stability of the bony structure. OsteoSelect® DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone. OsteoSelect® DBM Putty can be used as follows:

- Extremities
- Posterolateral spine
- Pelvis

Substantial Equivalence

This submission supports the position that OsteoSelect® DBM Putty is substantially equivalent to a number of pre-enactment and previously cleared devices, including:

OsteoSelect® Demineralized Bone Matrix Putty – Bacterin International, Inc. [510(k) K091321]

DBX® Demineralized Bone Matrix Putty – Musculoskeletal Transplant Foundation [510(k) K103784]

The 510(k) Notice contains summaries of manufacturing procedures, physical test results, shelf life testing, functionality (efficacy testing) results and biocompatibility testing that was previously conducted on the OsteoSelect® DBM Putty predicate. The methods used for processing the DBM used in the device have been tested and validated for viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and

genomes was evaluated. The processing methods were determined to provide significant viral inactivation potential for a wide range of viruses.

OsteoSelect® DBM Putty is osteoconductive and has been shown to have osteoinductive potential in an athymic rat model. Every final lot of OsteoSelect® DBM Putty is tested in an *in vivo* rat model for osteoinductive potential. It is unknown how the osteoinductivity potential in the rat model correlates with human clinical performance.

In addition, the Notice contains a report of an *in vivo* study that was conducted to support use of OsteoSelect® DBM Putty in the posterolateral spine.

The data presented demonstrate that the device is biocompatible and is suitable for its indicated use.

Conclusions

Bacterin International, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the OsteoSelect® DBM Putty. The materials from which the Bacterin device is fabricated have an established history of clinical use, and the device has been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Bacterin International, Incorporated
% Mr. Howard Schrayer
Regulatory Affairs Consultant
600 Cruiser Lane
Belgrade, Montana 59714

Letter dated: May 31, 2013

Re: K130498
Trade/Device Name: OsteoSelect® Demineralized Bone Matrix Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: March 19, 2013
Received: March 20, 2013

Dear Mr. Schrayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K130498

Device Name: OsteoSelect® Demineralized Bone Matrix Putty

Indications For Use:

OsteoSelect® DBM Putty is indicated for use as a bone void filler and bone graft substitute for voids or gaps that are not intrinsic to the stability of the bony strtucture. OsteoSelect® DBM Putty is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.

OsteoSelect® DBM Putty can be used as follows:

- Extremities
- Posterolateral spine
- Pelvis

Prescription Use ____X____ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130498

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: OSTEOSELECT™ Demineralized Bone Matrix Putty

Indications For Use:

OsteoSelect™ (DBM) Putty is indicated for use as a bone void filler and bone graft substitute for voids or gaps in the extremities and pelvis that are not intrinsic to the stability of bony structure. It is indicated for treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone.

Prescription Use_____X____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091321

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 DESCRIBED IN 21 CFR 1271.10

FEI: 3005168462

Other FDA Registrations:
Blood:
Devices: FEI: 3005031160
Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2022
Last Registration Receipt Date: 11/30/2021
Summary Report Print Date: 12/01/2021

Legal Name and Location:

Xtant Medical Holdings, Inc.
664 Cruiser Lane

Belgrade, Montana 59714
USA

Phone: 406-388-0480 **Ext.:** 1125

Reporting Official:

Rebecca L Lennemann, QA/RA Director
664 Cruiser Lane
Belgrade, Montana 59714
USA
Phone: 406-388-0480 Ext. 1125
rlennemann@xtantmedical.com

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI 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)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane							X		X			Dual layer membrane
Blood Vessel												
Bone			X		X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X	X	X			hMatrix Dermis, hMatrix PR
Tendon			X		X	X	X	X	X			Connective Tissue
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FDA information collection OMB Control number: 0910-0543, expiration date: 07/31/2023

Additional Information: No additional information provided.

Proprietary Name(s):	Bone	Traditional Allografts, OsteoSponge, OsteoWrap, OrbitalWrap, Milled Precision Allografts, 3Demin, BacFast HD, Atrix-C, Atrix-C Union, OsteoVive, OsteoVive Plus, OsteoFactor, OsteoMax. FiberOS, Hydragraft, BOB BEAST, AlloMate, Influx

FEI: 3005168462

Legal Name: Xtant Medical Holdings, Inc.

American Association of Tissue Banks

Herewith certifies
that the Institution named here

Bacterin International, Inc.
Belgrade, Montana

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

February 14, 2019 – April 10, 2022

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 14th day of February

AMERICAN ASSOCIATION OF TISSUE BANKS
AATB
ACCREDITED INSTITUTION

Lewis E. Barnes III

Chairman

President & Chief Executive Officer

Accreditation # 00157/5

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)

BACTERIN INTERNATIONAL INC.
600 CRUISER LN
ATTN: REBECCA LENNEMANN
BELGRADE MT 59714-9719

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.

BACTERIN INTERNATIONAL INC.
600 CRUISER LANE
BELGRADE MT 59714

OWNER(S):
BACTERIN INTERNATIONAL INC
XTANT MEDICAL HOLDINGS, INC

DIRECTOR(S):
SEAN BROWNE

TISSUE BANK ID Number: CTB 00080509
Issuance Date: September 24, 2021
Expiration Date: September 23, 2022

Robert J. Thomas

Robert J. Thomas, Acting Branch Chief
Laboratory Field Services

DELAWARE HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

February 11, 2021

Johnathan Reid
Xtant Medical
600 Cruiser Lane
Belgrade, MT 59714

Dear Johnathan Reid,

This letter confirms that **Xtant Medical** is registered with the Delaware Tissue Bank until April 30, 2022.

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,

Diane Smith

Diane Smith
Compliance Specialist
Delaware Division of Public Health
Bureau of Infectious Disease Prevention & Control
Ph. 302-744-1226 Fax 302-739-2550
DHSS_DPH_tissuebank@delaware.gov

View current license information at: Floridahealthfinder.gov

LICENSE #: 176
CERTIFICATE #: 1788

State of Florida

AGENCY FOR HEALTH CARE ADMINISTRATION
DIVISION OF HEALTH QUALITY ASSURANCE

Tissue Bank

Licensed

This is to confirm that Bacterin International, Inc. has complied with the rules and regulations adopted by the State of Florida, Agency for Health Care Administration, and authorized in Chapter 765, Florida Statutes, and is authorized to operate the following:

BACTERIN INTERNATIONAL INC
600 Cruiser Lane
Belgrade, MT 59714

Authorized Services: distribute tissues

EFFECTIVE DATE: 11/16/2021

EXPIRATION DATE: 11/15/2023

Simone Marstiller, Secretary
Agency for Health Care Administration

XTANT MEDICAL

888-886-9354
cs@xtantmedical.com
664 Cruiser Lane
Belgrade, MT 59714

September 09, 2021

RE: Florida Tissue Bank License #176 Expiration Extension

To whom it may concern,

The State of Florida, Office of the Governor has issued Executive Order Number 20-52 in response to the COVID-19 pandemic. This Executive Order granted 3-month extensions to renewals of Tissue Bank Licenses.

Although the physical copy of our Florida Tissue Bank License has an expiration of August 17, 2021, per the Executive Order, the expiration date has been extended to November 15, 2021. We have received the renewed license, however due to the executive order and extended expiration date, the effective date of the license is November 16, 2021.

If you have any questions or concerns with the license or expiration extension, please do not hesitate to contact me directly.

Sincerely,

R. Lennemann

Rebecca Lennemann
Director of Regulatory Affairs/Quality Assurance
406-388-0480 Ext. 1125
rlennemann@xtantmedical.com

STATE OF FLORIDA

OFFICE OF THE GOVERNOR

EXECUTIVE ORDER NUMBER 20-52

(Emergency Management - COVID-19 Public Health Emergency)

WHEREAS, Novel Coronavirus Disease 2019 (COVID-19) is a severe acute respiratory illness that can spread among humans through respiratory transmission and presents with symptoms similar to those of influenza; and

WHEREAS, in late 2019, a new and significant outbreak of COVID-19 emerged in China; and

WHEREAS, the World Health Organization previously declared COVID-19 a Public Health Emergency of International Concern; and

WHEREAS, in response to the recent COVID-19 outbreak in China, Iran, Italy, Japan and South Korea, the Centers for Disease Control and Prevention ("CDC") has deemed it necessary to prohibit or restrict non-essential travel to or from those countries; and

WHEREAS, on March 1, 2020, I issued Executive Order number 20-51 directing the Florida Department of Health to issue a Public Health Emergency; and

WHEREAS, on March 1, 2020, the State Surgeon General and State Health Officer declared a Public Health Emergency exists in the State of Florida as a result of COVID-19; and

WHEREAS, on March 7, 2020, I directed the Director of the Division of Emergency Management to activate the State Emergency Operations Center to Level 2 to provide coordination and response to the COVID-19 emergency; and

WHEREAS, as of March 9, 2020, eight counties in Florida have positive cases for COVID-19, and COVID-19 poses a risk to the entire state of Florida; and

WHEREAS, the CDC currently recommends community preparedness and everyday prevention measures be taken by all individuals and families in the United States, including voluntary home isolation when individuals are sick with respiratory symptoms, covering coughs and sneezes with a tissue and disposal of the tissue immediately thereafter, washing hands often with soap and water for at least 20 seconds, using of alcohol-based hand sanitizers with 60%-95% alcohol if soap and water are not readily available and routinely cleaning frequently touched surfaces and objects to increase community resilience and readiness for responding to an outbreak; and

WHEREAS, the CDC currently recommends mitigation measures for communities experiencing an outbreak including staying at home when sick, keeping away from others who are sick, limiting face-to-face contact with others as much as possible, consulting with your healthcare provider if individuals or members of a household are at high risk for COVID-19 complications, wearing a facemask if advised to do so by a healthcare provider or by a public health official, staying home when a household member is sick with respiratory disease symptoms if instructed to do so by public health officials or a health care provider; and

WHEREAS, as Governor, I am responsible for meeting the dangers presented to this state and its people by this emergency.

NOW, THEREFORE, I, RON DESANTIS, as Governor of Florida, by virtue of the authority vested in me by Article IV, Section (1)(a) of the Florida Constitution, Chapter 252, Florida Statutes, and all other applicable laws, promulgate the following Executive Order to take immediate effect:

Section 1. Because of the foregoing conditions, I declare a state of emergency exists in the State of Florida.

Section 2. I designate the Director of the Division of Emergency Management ("Director") as the State Coordinating Officer for the duration of this emergency and direct him to execute the State's Comprehensive Emergency Management Plan and other response, recovery, and mitigation plans necessary to cope with the emergency. Additionally, I designate the State Health Officer and Surgeon General as a Deputy State Coordinating Officer and State Incident Commander.

Pursuant to section 252.36(1)(a), Florida Statutes, I delegate to the State Coordinating Officer the authority to exercise those powers delineated in sections 252.36(5)-(10), Florida Statutes, which he shall exercise as needed to meet this emergency, subject to the limitations of section 252.33, Florida Statutes. In exercising the powers delegated by this Order, the State Coordinating Officer shall confer with the Governor to the fullest extent practicable. The State Coordinating Officer shall also have the authority to:

A. Seek direct assistance and enter into agreements with any and all agencies of the United States Government as may be needed to meet the emergency.

B. Designate additional Deputy State Coordinating Officers, as necessary.

C. Suspend the effect of any statute, rule, or order that would in any way prevent, hinder, or delay any mitigation, response, or recovery action necessary to cope with this emergency.

D. Enter orders as may be needed to implement any of the foregoing powers; however, the requirements of sections 252.46 and 120.54(4), Florida Statutes, do not apply to any such orders issued by the State Coordinating Officer; however, no such order shall remain in effect beyond the expiration of this Executive Order, to include any extension.

Section 3. I order the Adjutant General to activate the Florida National Guard, as needed, to deal with this emergency.

Section 4. I find that the special duties and responsibilities resting upon some State, regional, and local agencies and other governmental bodies in responding to the emergency may require them to suspend the application of the statutes, rules, ordinances, and orders they administer. Therefore, I issue the following authorizations:

A. Pursuant to section 252.36(1)(a), Florida Statutes, the Executive Office of the Governor may suspend all statutes and rules affecting budgeting to the extent necessary to provide budget authority for state agencies to cope with this emergency. The requirements of sections 252.46 and 120.54(4), Florida Statutes, do not apply to any such suspension issued by the Executive Office of the Governor; however, no such suspension shall remain in effect beyond the expiration of this Executive Order, to include any extension.

B. Each State agency may suspend the provisions of any regulatory statute prescribing the procedures for conduct of state business or the orders or rules of that agency, if strict compliance with the provisions of any such statute, order, or rule would in any way prevent, hinder, or delay necessary action in coping with the emergency. This includes, but is not limited to, the authority to suspend any and all statutes, rules, ordinances, or orders which affect leasing, printing, purchasing, travel, and the condition of employment and the compensation of employees. For the purposes of this Executive Order, "necessary action in coping with the emergency" means any emergency mitigation, response, or recovery action: (1) prescribed in the State Comprehensive Emergency Management Plan ("CEMP"); or (2) ordered by the State Coordinating Officer. The requirements of sections 252.46 and 120.54, Florida Statutes, shall not apply to any such suspension issued by a State agency; however, no such suspension shall remain in effect beyond the expiration of this Executive Order, to include any extensions.

C. In accordance with section 465.0275, Florida Statutes, pharmacists may dispense up to a 30-day emergency prescription refill of maintenance medication to persons who reside in an area or county covered under this Executive Order and to emergency personnel who have been activated by their state and local agency but who do not reside in an area or county covered by this Executive Order.

D. In accordance with section 252.38, Florida Statutes, each political subdivision within the State of Florida may waive the procedures and formalities otherwise required of the political subdivision by law pertaining to:

1) Performance of public work and taking whatever prudent action is necessary to ensure the health, safety, and welfare of the community;

2) Entering into contracts; however, political subdivisions are cautioned against entering into time and materials contracts without ceiling as defined by 2 CFR 200.318(j) or cost plus percentage contracts as defined by 2 CFR 200.323(d);

3) Incurring obligations;

4) Employment of permanent and temporary workers;

5) Utilization of volunteer workers;

6) Rental of equipment;

7) Acquisition and distribution, with or without compensation, of supplies, materials, and facilities; and,

8) Appropriation and expenditure of public funds.

E. All State agencies responsible for the use of State buildings and facilities may close such buildings and facilities in those portions of the State affected by this emergency, to the extent necessary to meet this emergency. I direct each State agency to report the closure of any State

building or facility to the Secretary of the Department of Management Services. Under the authority contained in section 252.36, Florida Statutes, I direct each County to report the closure of any building or facility operated or maintained by the County or any political subdivision therein to the Secretary of the Department of Management Services. Furthermore, I direct the Secretary of the Department of Management Services to:

1) Maintain an accurate and up-to-date list of all such closures; and,

2) Provide that list daily to the State Coordinating Officer.

Section 5. I find that the demands placed upon the funds appropriated to the agencies of the State of Florida and to local agencies are unreasonably great and the funds currently available may be inadequate to pay the costs of coping with this emergency. In accordance with section 252.37(2), Florida Statutes, I direct that sufficient funds be made available, as needed, by transferring and expending moneys appropriated for other purposes, moneys from unappropriated surplus funds, or from the Budget Stabilization Fund.

Section 6. All State agencies entering emergency final orders or other final actions in response to this emergency shall advise the State Coordinating Officer contemporaneously or as soon as practicable.

Section 7. Medical professionals and workers, social workers, and counselors with good and valid professional licenses issued by states other than the State of Florida may render such services in Florida during this emergency for persons affected by this emergency with the condition that such services be rendered to such persons free of charge, and with the further condition that such services be rendered under the auspices of the American Red Cross or the Florida Department of Health.

Section 8. All activities taken by the Director of the Division of Emergency Management and the State Health Officer and Surgeon General with respect to this emergency before the issuance of this Executive Order are ratified. This Executive Order shall expire sixty days from this date unless extended.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Florida to be affixed, at Tallahassee, this 9th day of March, 2020.

RON DESANTIS, GOVERNOR

ATTEST:

SECRETARY OF STATE

FILED
2020 MAR -9 PM 5:52

RON DESANTIS
GOVERNOR

SIMONE MARSTILLER
SECRETARY

September 9, 2021

Email: Rlennemann@Xtantmedical.Com

Sean Browne, Agency Director
Bacterin International Inc
600 Cruiser Lane
Belgrade, MT 59714

File Number: 41950171
License Number: 176
Provider Type: Organ and Tissue Procurement

RE: Facility locator at 600 Cruiser Lane, Belgrade

Dear Administrator:

The enclosed Organ and Tissue Procurement license with license number 176 and certificate number 1788 is issued for the above provider effective November 16, 2021 through November 15, 2023. 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 and In-Home Services 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 - 4372 or by email at Dana.Hines@ahca.myflorida.com.

Sincerely,

Dana Hines

Laboratory and In-Home Services Unit
Division of Health Quality Assurance

RON DESANTIS
GOVERNOR

MARY C. MAYHEW
SECRETARY

August 14, 2019

Ron Berlin, Agency Director
Bacterin International Inc.
600 Cruiser Lane
Belgrade, MT 59714

File Number: 41950171
License Number: 176
Provider Type: Organ And Tissue Procurement

RE: 600 Cruiser Lane, Belgrade

Dear Administrator:

The enclosed Organ and Tissue Procurement license with license number 176 and certificate number 1537 is issued for the above provider effective August 18, 2019 through August 17, 2021. 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 and In-Home Services 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

Linda Lovette-Leonard
Health Services & Facilities Consultant
Laboratory and In-Home Services Unit
Division of Health Quality Assurance

IDPH
ILLINOIS DEPARTMENT OF PUBLIC HEALTH

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

Effective Date: **May 01, 2021**

Expires: May 01, **2022**

Sean Brown, Facility Director
Xtant Medical
664 Cruiser Lane
Belgrade, MT 59714

Registration Number 1611

State of Illinois
2021
Sperm/Tissue Bank Registration

Xtant Medical

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,

Brandon Rakowski
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
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: TB1366 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:

BACTERIN INTERNATIONAL INC
600 CRUISER LANE
BELGRADE, MT 59714

Director: Dr DUKE KASPRISIN
Owner: BACTERIN INTERNATIONAL HOLDINGS

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

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

Skin Bank:
Dermis

CONTROL: **74617**

Patricia Tomasko May MD
Director

Falsification of a license shall subject the perpetrator to criminal prosecution and the impostition 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

Facility ID: 1352

Tissue Bank Director:
Rebecca Lenneman, CTBS
Director of RA/QA

Medical Director:
Duke O. Kasprisin, M.D.

Bacterin International, Inc.
600 Cruiser Lane
Belgrade, MT 59714

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

Comprehensive Tissue Procurement Service	Musculoskeletal tissue Pericardium
Tissue Processing Facility	Musculoskeletal tissue Pericardium
Tissue Storage Facility	Skin Tissue Amniotic membrane

Issued: **July 7, 2021**

Expires: **August 1, 2023**

Owner: Xtant Medical Holdings, Inc.

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

DOH-3908 (04/2001)

LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

DISTRIBUTOR OF LEGEND DRUGS OR LEGEND DEVICES

SUB-TYPE: Standard Distributor

BACTERIN INTERNATIONAL INC. dba Xtant Medical

License No. **6383** effective **01/01/2022** *(Original issue date: 09/15/2009)*, Expiring **12/31/2022**
distributing from **600 Cruiser Lane, Belgrade, MT, 59714**
BUSINESS ADDRESS: 600 CRUSIER LANE, BELGRADE, MT, 59714
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.drugboard.la.gov Email: admin@drugboard.la.gov

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.

Oregon Health Authority

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

May 16, 2019

Mr. Ron Berlin,
Bacterin International, Inc
600 Cruiser Lane
Belgrade, MT 59714

Dear Mr. Berlin:

This letter is to notify you that Bacterin International, Inc has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on June 20, 2022.

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

Sincerely,

Lisa Humphries
Administrativer 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