



Health Care Regulation and Quality Improvement
800 NE Oregon Street, Suite 465
Portland, Oregon 97232
971-673-0540
971-673-0556 (Fax)
mailbox.inhomecare@odhsoha.oregon.gov

August 15, 2023

Kristen Stottlemeyer
BioXtek, LLLC
316 Ne 1st Street
Pompano Beach, FL 33060

Dear Ms. Stottlemeyer:

This letter is to notify you that Bioxtek, LLC has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on August 15, 2026.

Thank you for your cooperation. Should you have any questions, please contact our office at the above phone number or email address.

Sincerely,

Oregon Procurement Organizations/Tissue Bank Registry Staff
Oregon Health Authority
Public Health Division
Health Care Regulation and Quality Improvement

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

**OREGON REVISED STATUTES
2007**

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

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

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

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

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

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

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

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

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

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

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

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

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

441.080 [Repealed by 1971 c.730 §25]

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

441.082 Registration of organ procurement organization, tissue bank

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

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

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

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

(a) Register with the department;

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

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

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

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

Note: See note under 441.079.

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

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

Received
 JUL 31 2023

Health Care Regulation
 and Quality Improvement



Organ Procurement Organization Registration Form

Type of Facility / Organization	
New facility? <input type="radio"/>	Renewal? <input type="radio"/>
<input checked="" type="radio"/> Tissue Bank <input type="radio"/> Eye Bank	Please attach evidence of current FDA registration.
<input type="radio"/> Health Care Facility Performing Transplants	Please attach evidence of current organ procurement and transplantation network membership

Facility / Organization Information		
Legal Name: BioXtek, LLC		
DBA Name (if applicable):		
Physical Address, City, State & ZIP: 316 NE 1st Street, Pompano Beach, FL 33060		
Phone: 954-247-1977	Fax:	County: Broward
Mailing Address (if different from above): 401 E Las Olas, Suite 130-157, Ft Lauderdale, FL 33301		
Facility / Organization Email: info@bioXtek.com		Tax ID#: 88-2549080

Administrator Information		
Name of Administrator(s): Kristen Stottlemyer		
Address, City, State & ZIP: 316 NE 1st St. Pompano Beach, FL 33060		
Phone: 321-696-5088	Fax:	County: Broward
Email: KristenS@bioXtek.com		

Contact Person for Organ Procurement or Transplant Program (If applicable)		
Name: n/a		
Phone:	Email:	Fax:

I declare, under penalties of perjury, that I have examined this application and all attachments and that to the best of my knowledge and belief, this information is true, correct and complete. I will notify Health Care Regulation and Quality Improvement, in writing, of any changes in this information within 30 days of any such change.



 Administrator's Signature
 Quality Manager

 Print Title

Kristen Stottlemyer

 Print Name
 27 JUL 23

 Date (mm/dd/year)

Mail application to: Oregon Health Authority
 HFLC
 800 NE Oregon St., Suite 465
 Portland, OR 97232

Questions about this application? Phone: 971-673-0540 Email: mailbox.hclc@odhsoha.oregon.gov



U.S. FOOD & DRUG ADMINISTRATION

FDA Home Page | Contact eHCTERS Technical Support | Log Out

eHCTERS - Registration Information

Submitted Registration Information

This information has been submitted to the FDA
 Please Remember Your Confirmation Number to Reference this registration submission
YOUR CONFIRMATION NUMBER IS: 60968
 Please print this document and maintain as confirmation of your submission.
 This application is no longer accessible using your pre-confirmation number.

FEI: Unknown

Other FDA Registrations

- Blood
- Devices
- Drug

Reason for Submission

- Initial Registration/Listing
- Annual Registration/Listing
- Change in Information
- In-Activate Registration

Physical Location

Legal Name: BioXtek, LLC
 Street Address: 316 NE 1st Street
 Florida
 City: Pompano Beach
 State: Florida
 Postal Code: 33060
 Country: UNITED STATES
 Phone: 321-696-5088 ext.

Reporting Official Information

First Name: Kristen
 Last Name: Stottlemeyer
 Title: Quality Manager
 Phone: 321-696-5088 Ext.
 E-Mail Address: kristens@bioxtek.com

Mailing Address of Reporting Official

Institution Name: BioXtek, LLC
 Street Address: 316 NE 1st Street
 Florida
 City: Pompano Beach
 State: Florida
 Postal Code: 33060
 Country: UNITED STATES

HCT/P Listing Information

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names
Amniotic Membrane	X			Sanoplast ECM, IMPAX, Zenith, Orion

HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

[Select New Establishment](#)

[CBER On-Line Main Menu](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

eHCTERS v02.13.01
Updated 11/20/2020

FDA information collection OMB Control number: 0910-0543
Expiration Date: 07/31/2023

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FDA / Center for Biologics Evaluation and Research

Status of registration for BioXtek

CBER Tissue Registration <tissuereg@fda.hhs.gov>
To: Kristen Stottlemyer <kristens@bioxtek.com>

Tue, Jun 20, 2023 at 3:24 PM

Greetings Ms. Stottlemyer,

Thank you for your email query. I understand that you submitted a pre-registration request (May 03, 2023) for your establishment.

Your establishment registration status is 'Pre-Registered' and will be review and assign a permanent FEI# by the district. You will be notified once the status changes to 'Registered' and a FEI number has been assigned. The review process takes several weeks. Thank you for your patience.

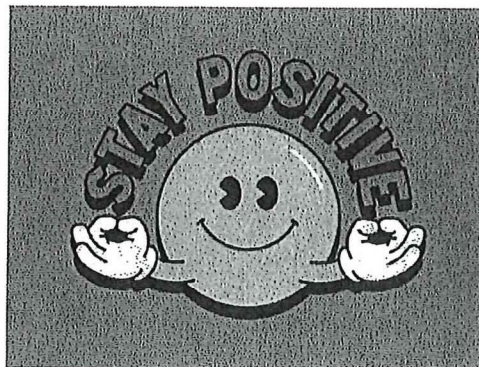
Please note that your establishment can begin handling HCT/Ps while the pre-registration status is 'Pre-Registered' in eHCTERS.

Kind Regards,

Mrs. Aletha Davis-Knight

Mrs. Aletha Davis-Knight

Regulatory Information Specialist



This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time, but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any

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: 3027649380

Other FDA Registrations:
 Blood:
 Devices:
 Drugs:

Reason For Last Submission: Initial Registration/Listing
 Last Annual Registration Year: 2023
 Last Registration Receipt Date: 08/10/2023
 Summary Report Print Date: 08/10/2023

Legal Name and Location:
 BioXtek, LLC
 316 NE 1st Street
 Florida
 Pompano Beach, Florida 33060
 USA
 Phone: 321-696-5088 Ext.:

Reporting Official:
 Kristen Stollmeyer, Quality Manager
 316 NE 1st Street
 Pompano Beach, Florida 33060
 USA
 Phone: 321-696-5038 Ext.
 kristens@bioxtek.com

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)).

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			
Amniotic Membrane					X	X	X	X			***See full text on next page.
Blood Vessel											
Bone											
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											
Tendon											
Testicular Tissue											
Tooth Pulp											
Umbilical Cord Tissue											

Additional Information: No additional information provided.

Proprietary Name(s): Amniote Membrane	Sanoplast ECM, IMPAX, Zenith, Orion
---------------------------------------	-------------------------------------

FEI: 3027649380

Legal Name:

BioXtact, LLC