



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

March 15th, 2022

Dawn Holts  
Amnio Technology, LLC  
22510 North 18th Drive  
Phoenix, AZ 85027

Dear Ms. Holts:

This letter is to notify you that Amnio Technology, LLC has been placed on the Oregon Procurement Organizations/Tissue Bank Registry. This registration is in effect for three years ending on May 2, 2025.

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

Sincerely,

Macie P. Coronel  
Licensing Specialist  
Oregon Health Authority  
Public Health Division  
Health Care Regulation and Quality Improvement

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

**OREGON REVISED STATUTES  
2007**

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

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

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

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

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

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

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

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

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

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

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

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

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

**441.080** [Repealed by 1971 c.730 §25]

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

**441.082 Registration of organ procurement organization, tissue bank**

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

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

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

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

(a) Register with the department;

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

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

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

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

**Note:** See note under 441.079.

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

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

## Organ Procurement Organization Registration Form

Type of Facility / Organization	
New facility? <input type="radio"/>	Renewal? <input checked="" type="checkbox"/>
<input 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: Amnio Technology, LLC	
DBA Name (if applicable):	
Physical Address, City, State & ZIP: 22510 N 18 <sup>th</sup> Drive Phoenix, AZ 85027	
Phone: 888-232-8550	Fax: 888-232-6750
County: Maricopa	
Mailing Address (if different from above):	
Facility / Organization Email: <a href="mailto:Quality@amniotechnology.com">Quality@amniotechnology.com</a>	

Administrator Information	
Name of Administrator(s): Dawn Holts	
Address, City, State & ZIP: 22510 N 18 <sup>th</sup> Drive Phoenix, AZ 85027	
Phone: 623-344-1760	Fax: 888-232-6750
County: Maricopa	
Email: <a href="mailto:DHolts@amniotechnology.com">DHolts@amniotechnology.com</a>	

Contact Person for Organ Procurement or Transplant Program (If applicable)	
Name: Kate Shanks	
Phone: 623-344-1761	Email: <a href="mailto:kshanks@amniotechnology.com">kshanks@amniotechnology.com</a>
Fax: 888-232-6750	

*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  
 Director of Operations  
 \_\_\_\_\_  
 Print Title

Dawn Holts  
 \_\_\_\_\_  
 Print Name  
 05/30/2024  
 \_\_\_\_\_  
 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@state.or.us](mailto:mailbox.hclc@state.or.us)

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: 3011545418

Other FDA Registrations:  
 Blood:  
 Devices:  
 Drugs:

Reason For Last Submission: Annual Registration/Listing  
 Last Annual Registration Year: 2024  
 Last Registration Receipt Date: 11/16/2023  
 Summary Report Print Date: 12/01/2023

Legal Name and Location:

Amnio Technology, LLC  
 22510 N 18th Drive

Phoenix, Arizona 85027  
 USA

Phone: 888-232-8550

Ext.:

Reporting Official:

Kate L Shanks, Regulatory Affairs Manager  
 22510 N 18th Drive

Phoenix, Arizona 85027  
 USA

Phone: 623-344-1761 Ext.  
 kshanks@amniotechnology.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			
Amniotic Membrane										
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										

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**Additional Information:**

Ammio Membrane:  
PallGen Membrane  
PallGen Hydromembrane  
PallGen XPlus Membrane  
PallGen XPlus Hydromembrane  
PallGen Dual Layer Membrane  
PallGen Dual Layer X-Membrane  
KardiaMembrane

**Proprietary Name(s):**

FEI: 3011545418

Legal Name:

Ammio Technology, LLC