

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.

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]

PUBLIC HEALTH DIVISION

Health Care Regulation and Quality Improvement Section Health Facility Licensing and Certification Program healthoregon.org/hfic



Organ Procurement Organization Registration Form

Type of Facility / Organization	
New facility?	Renewal?
Tissue Bank Eye Bank	Please attach evidence of current FDA registration.
Health Care Facility Performing Transplants	Please attach evidence of current organ procurement and transplantation network membership
Facility / Organization Informat	ion
Legal Name: Amnio Techno	
DBA Name (if applicable):	
Physical Address, City, State & Z	IP: 22510 N 18th Drive Phoenix, AZ 85027
Phone: 888-232-8550	Fax: 888-232-6750 County: Mari Lopa
Mailing Address (if different from	above):
Facility / Organization Email: ()	valityDamniotechnology, com
	Jacobs Jacobs Jacobs Contraction of the Contraction
Administrator Information	
Name of Administrator(s): Daw	on Holts
Address, City, State & ZIP: 225	O N 18th Drive Phoenix, AZ 85027
Phone: 623-344-1760	Fax: 888-232-6750 County: Mari LOPA
Email: Dholts Damniotech	nology, com
Contact Person for Organ Proc	urement or Transplant Program (If applicable)
Name: Katl Shanks	
Phone: 623-344-176	Email: KShanks Jamnibyy, Fax: 888-232-6750
I declare, under penalties of perjury, best of my knowledge and belief, this Regulation and Quality Improvement change. Administrator's Signature Divicitory of Copy	that I have examined this application and all attachments and that to the information is true, correct and complete. I will notify Health Care in writing, of any changes in this information within 30 days of any such
Print Title	Date (mm/dd/year)
Mail	application to: Oregon Health Authority

Questions about this application? Phone: 971-673-0540 Email: mailbox.hclc@state.or.us

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800 NE Oregon St., Suite 465

Portland, OR 97232

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Phone 83027	Legal Name and Location: Amnio Technology, LLC 22510 N 18th Drive		Reporting Official: Kate L Shanks, Regulatory Affairs 22510 N 18th Drive	Manager		Satollito Ro Parent Mani Testing For	covory Establishn ufacturing Establi Micro-Organisms	
HCTP(s) HCT	Phoenix, Arizona 85027		Phoenk, Arizona 85027 USA Phone: 623-344-1761 Ext kshanks@amriotechnology.com			Note: FDA acconstitute a droug	ceptance of an est etermination that a ulations or that the	ablishment registration and HCTIP listing does not nestablishment is in compliance with applicable HCTIP is licensed or approved by FDA (21 CFR
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PalinGen XPlus Membrane
PalinGen XPlus Hydromembrane
PalinGen Dual Layer Membrane
PalinGen Dual Layer Membrane
PalinGen Dual Layer X-Membrane
RaidiaMembrane

Proprietary Name(s):

3011545418

HE

Legal Name;

Amnio Technology, LLC

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026 Page 2 of 2