

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3011545418	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	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
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<b>Legal Name and Location:</b>  Amnio Technology, LLC 22510 N 18th Drive  Phoenix, Arizona 85027 USA  Phone: 888-232-8550 <b>Ext.:</b>	<b>Reporting Official:</b> Kate L Shanks, Regulatory Affairs Manager 22510 N 18th Drive Phoenix, Arizona 85027 USA Phone: 623-344-1761 Ext. kshanks@amniotechnology.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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)).
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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			continues 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:**

Amniotic Membrane:  
PalinGen Membrane  
PalinGen Hydromembrane  
PalinGen XPlus Membrane  
PalinGen XPlus Hydromembrane  
PalinGen Dual Layer Membrane  
PalinGen Dual Layer X-Membrane  
KardiaMembrane

**Proprietary Name(s):**

FEI: 3011545418

Legal Name:

Amnio Technology, LLC

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3017393669	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	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
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<b>Legal Name and Location:</b>  Amnio Technology, LLC 1125 W. Pinnacle Peak Bldg #1, AT Suite  Phoenix, Arizona 85027 USA  Phone: 888-232-8550 <b>Ext.:</b>	<b>Reporting Official:</b> Kate L Shanks, Regulatory Affairs Manager 22510 N 18th Street Phoenix, Arizona 85027 USA Phone: 623-344-1761 Ext. kshanks@amniotechnology.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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)).
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Pericardium												
Peripheral Blood Mononuclear Cells												
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Skin												
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Testicular Tissue												
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PalinGen Dual Layer Membrane  
PalinGen Dual Layer X-Membrane  
KardiaMembrane

<b>Proprietary Name(s):</b> Amniotic Membrane	Continued in Additional Information
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