

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: 3017393669	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 11/15/2022 Summary Report Print Date: 12/01/2022
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Legal Name and Location: Amnio Technology, LLC 1125 W. Pinnacle Peak Bldg #1, AT Suite Phoenix, Arizona 85027 USA Phone: 888-232-8550 Ext.:	Reporting Official: Kate L Shanks, Regulatory Affairs Manager 22510 N 18th Street 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)).
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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			***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: Amniotic Membrane:
PalinGen Membrane
PalinGen Hydromembrane
PalinGen XPlus Membrane
PalinGen XPlus Hydromembrane
KardiaMembrane
SXBarrier
SXBarrier-Wet
ASGBarrier
ASGBarrier-Wet
SuiGen Membrane
SuiGen Hydromembrane
SuiGen XPlus Membrane
SuiGen XPlus Hydromembrane
STRATOGEN Membrane
STRATOGEN Plus Membrane
PalinGen Dual Layer Membrane
PalinGen Dual Layer X-Membrane
Zenith Graft Membrane
Axolotl Biologix Single Layer Graft
Axolotl Biologix Dual Layer Graft

Proprietary Name(s): Amniotic Membrane	Continued in Additional Information
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Legal Name:

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HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
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Ovarian Tissue												
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Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Amniotic Membrane:
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PalinGen XPlus Membrane
PalinGen XPlus Hydromembrane
KardiaMembrane
SXBarrier
SXBarrier-Wet
ASGBarrier
ASGBarrier-Wet
SuiGen Membrane
SuiGen Hydromembrane
SuiGen XPlus Membrane
SuiGen XPlus Hydromembrane
STRATOGEN Membrane
STRATOGEN Plus Membrane
PalinGen Dual Layer Membrane
PalinGen Dual Layer X-Membrane
Zenith Graft Membrane
Axolotl Biologix Single Layer Graft
Axolotl Biologix Dual Layer Graft
AlonShield Dc.02/17
AlonShield-Wet Dc.02/17
Nanofactor Membrane Dc.12/16
AlloShield Dc.05/15
AlloShield Dry Dc.05/15
XWRAP ECM Dc.01/15
XWRAP HYDRO Dc.01/15
XWRAP DRY Dc.01/15
XWRAP HYDRO PLUS Dc.01/15

Proprietary Name(s):

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