

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: 2025 Last Registration Receipt Date: 11/18/2024 Summary Report Print Date: 12/05/2024
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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)).
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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
Abiomend Membrane
Abiomend Hydromembrane
Abiomend Xplus Membrane
Abiomend Xplus Hydromembrane
Amnio Burgeon Membrane
Amnio Burgeon Hydromembrane
Amnio Burgeon Dual-Layer Membrane
Dual Layer Amnio Burgeon X-Membrane
Amnio Burgeon Xplus Membrane
Amnio Burgeon Xplus Hydromembrane
BioHealXL Membrane
PalinGen Tri-Layer Membrane

Proprietary Name(s):

FEI: 3011545418

Legal Name:

Amnio Technology, LLC