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: 1000100754

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2026
Last Registration Receipt Date: 12/26/2025
Summary Report Print Date: 01/09/2026

Legal Name and Location:

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Reporting Official:

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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	Label	Distribute			
Amniotic Membrane			X		X	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone			X		X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage										01-JAN-24		
Cornea												
Dura Mater												
Embryo												
Fascia			X		X	X	X	X	X			TranZgraft
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			X		X	X	X	X	X			TranZgraft, ZelleGraft
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium										01-DEC-19		
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X		X	X	X	X	X			***See full text on next page.
Tendon			X		X	X	X	X	X			TranZgraft, ZelleGraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue										28-MAY-21		

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

Additional Information: No additional information provided.

Proprietary Name(s):		
	Amniotic Membrane	AlloAid Amniotic Allograft Cover, AlloAid StimDisk, AlloGuide GF, AltiPly, AltiPly Duo, AltiPly Lite, AmnioRepair, Empliq Amnio-Duo, Empliq Amnio-Lite, Empliq Placental, ReNuCelz, Stemnios Matrix, StemStrip, Xcell Amnio Matrix, Xcellerate, XcellePATCH, XcellerEYES, ZelleAMNIO
	Bone	AlloAid BioNail, AlloAid DIP, AlloAid Nail, AlloAid PIP, AlloStat GFX Bone Fiber Matrix, CoreCell, D-FIBER, JoinTac, LD-FIBER, OmniArch Anatomic Wedge System, Optimus V, OsteSpine, SILO, Spectrum C, Spectrum Interbody, TENFUSE, TranZgraft, ViMax Fiber Matrix, X-Graft, Xtant Medical Cancellous Chips, X-Wedge System
	Skin	AcelloDerm, AcelloDerm-DL, AlloAid DM, AlloStat Deep Dermal Matrix, Coll-e-Derm, Colle-Derm RT, DermaSpan ACD, DermaSpanR, DermiPly, Empliq Dermal, IntéguPly Acellular Dermis, SimpliDerm, TigoDerm, XcelleDERM

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