

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: 3006813973	Other FDA Registrations: Blood: Devices: FEI: 3008812241 Drugs:	Reason For Last Submission: Change in Information Last Annual Registration Year: 2022 Last Registration Receipt Date: 03/04/2022 Summary Report Print Date: 03/14/2022
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Legal Name and Location: MTF Jessup Distribution Center 1175 Mid Valley Drive Olyphant, Pennsylvania 18447 USA Phone: 570-496-3400 Ext.:	Reporting Official: Joel Osborne, Vice President, Regulatory Affairs Attn: Joel Osborne 125 May Street Suite 300 Edison , New Jersey 08837 USA Phone: 732-661-0202 Ext. ra_licenses@mtf.org	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							X		X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage							X		X			
Cornea												
Dura Mater												
Embryo												
Fascia							X		X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							X		X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							X		X			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X		X			***See full text on next page.
Tendon							X		X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue										31-MAY-21		

Additional Information: No additional information provided.

Proprietary Name(s): Amniotic Membrane	AmnioBand Viable, AmnioBand Particulate, VersaShield, Enhance, Blockade, Essence, AmnioBand Matrix, AmnioBand Membrane, Salera
Bone	Profile, Vertefill, Oracle, Alloquent, ARCH ODL, Conform Cube, Luminary PLIF, Luminary T-PLIF, Luminary CC-ALIF, Trinity Evolution, Trinity ELITE, CartiMax, MOPS, Conform Sheet, Conform Flex, Cartilage Allograft Matrix, Prime DBM, Prime HD DBM, DBX Natural Fiber Strip, Threaded Facet Dowel, fiberFUSE Advanced, fiberFUSE Strip, Kore Fiber Moldable, Kore Fiber Strip, Allofiber DBF, Biologic Allograft Chain, Prolix, Incite Cortical Fibers
Skin	FlexHD Pliable, FlexHD Pliable Perforated, FlexHD Pliable Shaped, FlexHD Pliable MAX, FlexHD Pliable PRE, FlexHD Structural, FlexHD Structural Diamond, AlloPatch Pliable, Leneva, RenuvaHD, SomaGen, AlloPatchHD, PerioDerm, Renuva

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