

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: Annual Registration/Listing
Last Annual Registration Year: 2020
Last Registration Receipt Date: 10/15/2020
Summary Report Print Date: 11/16/2020

Legal Name and Location:

MTF Jessup Distribution Center
1175 Mid Valley Drive

Olyphant, Pennsylvania 18447
USA

Phone: 570-496-3400

Ext.:

Reporting Official:

Keith Alderman, Vice President, Quality Management
Attn: Keith Alderman
125 May Street Suite 300
Edison , New Jersey 08837
USA
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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			***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					X		X	X	X			

Additional Information: Umbilical Cord Tissue: Proprietary Name: MOTYS

Proprietary Name(s): Amniotic Membrane	AmnioBand Viable, AmnioBand Particulate, AmnioBand, VersaShield, Enhance, Blockade, Essence
Bone	Conform Sheet, Luminary CC-ALIF, Luminary T-PLIF, ARCH ODL, VerteFill, Conform Flex, ENACT, Conform Putty, Conform Cube, Trinity Evolution, Trinity ELITE, Luminary PLIF, Cartilage Allograft Matrix, Prime DBM, Oracle, Profile, AlloQuent, CartiMax, Prime HD DBM, DBX Natural Fiber Strip, fiberFuse, MOPS
Skin	FlexHD Pliable, FlexHD Pliable Perforated, FlexHD Pliable Shaped, FlexHD Structural, FlexHD Structural Diamond, AlloPatch Pliable, AlloPatchHD, BellaDerm, PerioDerm, FlexHD Pliable MAX, Renuva, AlloPatch Pliable Meshed, Allograft Adipose Matrix, FlexHD Pliable PRE, SomaGen, RenuvaHD, Leneva

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