## 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**

Ext.:

FEI: 1000307092

Reporting Official:

Other FDA Registrations: Blood:

Devices:FEI: 1000307092

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/07/2023 Summary Report Print Date: 12/15/2023

Legal Name and Location:

Musculoskeletal Transplant Foundation d/b/a/ MTF Biologics

1232 Mid Valley Drive

Jessup, Pennsylvania 18434

USA

Phone: 570-496-3400

Joel Osborne, Vice President, Regulatory Affairs Attn: Joel Osborne

Edison Corporate Center 125 May St., Suite 300 Edison, New Jersey 08837

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)).

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone					Х	X	Х	Х				***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage					Х	Х	Х	Х				
Cornea												
Dura Mater												
Embryo												
Fascia					Х	Х	Х	Х				
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament					X	х	Х	Х				
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium					Х	Х	Х	Х				
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon					Х	Х	Х	Х				
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FEI:

Proprietary Name(s):	Bone	Conform Sheet, Luminary CC-ALIF, Luminary T-PLIF, ARCH ODL, VerteFill, Conform Flex, Conform Cube, Trinity Evolution, Trinity ELITE, Luminary PLIF, Cartilage Allograft Matrix, Prime DBM, Oracle, Profile, AlloQuent, CartiMax, Prime HD DBM, DBX Natural Fiber Strip, MOPS, Allio, AlloAid Evans Wedge, AlloAid Cotton Wedge, AlloAid SubChon, AlloAid QF Cortical, AlloAid Backfill Plug, Vallos Granules, Vallos f Deminerialized Cortical Fibers, Cartimax FA, Threaded Facet Dowel, fiberFUSE Advanced, fiberFUSE Strip, Kore Fiber Moldable, Kore Fiber Strip, Allofiber DBF, BAC: Biologic Allograft Chain, Prolix, MTF Fiber,
		MTF Fiber Strip, Virtuos

FEI: 1000307092 Legal Name: Musculoskeletal Transplant Foundation d/b/a/ MTF Biologics

Additional Information:

No additional information provided.