## 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: 3011400049

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/20/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

Musculoskeletal Transplant Foundation d/b/a/ MTF Biologics

3495 Winton Place

Building E Suite 110

Rochester, New York 14623

USA

Phone: 585-441-9763

Reporting Official:

Joel Osborne, Vice President, Regulatory Affairs

125 May Street

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)).

					Establishr	nent Functio	ons					
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			Х									
Blood Vessel			Х									
Bone			Х									
Cardiac Tissue - non-valved												
Cartilage			Х									
Cornea												
Dura Mater												
Embryo												
Fascia			Х									
Heart Valve			Х									
HPC Apheresis												
HPC Cord Blood												
Ligament			Х									
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium			Х									
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			Х									
Tendon			Х									
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue										31-MAY-21		

Additional Information:	No additional information	orovided

Proprietary Name(s):

FEI: 3011400049 Legal Name: Musculoskeletal Transplant Foundation d/b/a/ MTF Biologics