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: 3003447829

Reporting Official:

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2023

No

Last Annual Registration Year: 2023
Last Registration Receipt Date: 11/16/2022
Summary Report Print Date: 12/01/2022

Legal Name and Location:

Edison, New Jersey 08837

Phone: 303-691-3363

Statline, division of MTF Biologics

125 May Street

USA

Lisa D'Agostino, Manager, Quality Systems 125 May Street Edison, New Jersey 08837

USA

Phone: 303-691-3363 Ext. 2887

Imdagostino@statline.org

Satellite Recovery Establishment:

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)).

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

Additional Information:	Statline's operations are fully remote. There is no physical location for our donor screening call center, and all administrative employees are similarly remote staff.

Proprietary Name(s):

FEI: 3003447829 Legal Name: Statline, division of MTF Biologics