

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: 3003447829 Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/16/2023 Summary Report Print Date: 12/01/2023
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Legal Name and Location: Statline, division of MTF Biologics 125 May Street Edison, New Jersey 08837 USA Phone: 303-691-3363	Reporting Official: Deborah Tucker, Lead Quality Specialist 125 May Street Edison, New Jersey 08837 USA Phone: 303-691-3363 Ext. dtucker@statline.org	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: 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			
Ambiotic Membrane											
Blood Vessel			X								
Bone			X								
Cardiac Tissue - non-valved			X								
Cartilage			X								
Cornea											
Dura Mater											
Embryo											
Fascia			X								
Heart Valve			X								
HPC Apheresis											
HPC Cord Blood											
Ligament			X								
Nerve Tissue			X								
Oocyte											
Ovarian Tissue											
Pancreatic Islet Cells - autologous											
Parathyroid											
Pericardium			X								
Peripheral Blood Mononuclear Cells											
Peritoneal Membrane											
Sclera			X								
Semen											
Skin			X								
Tendon			X								
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:

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