

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: 2025 Last Registration Receipt Date: 11/15/2024 Summary Report Print Date: 12/05/2024
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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 Ext.:	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.: 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	Distribute			
Amniotic Membrane												
Blood Vessel			X									
Bone			X									
Cardiac Tissue - non-valved												
Cartilage			X									
Cornea			X									
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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