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: 3023813954

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2025
Last Registration Receipt Date: 12/02/2024
Summary Report Print Date: 12/05/2024

Legal Name and Location:

ReproTech LLC 204 Spring Hill Road Suite 110

Trumbull, Connecticut 06611

USA

Phone: 203-816-5598

Reporting Official:

Amy S Erickson Hagen, QA Officer

204 Spring Hill Road

Suite 110

Trumbull, Connecticut 06611

USA

Phone: 612-747-4154 Ext. aehagen@reprotech.com

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												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo	Anonymous, Directed, SIP						Х	Х	Х			
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte	Anonymous, Directed, SIP						Х	Х	Х			
Ovarian Tissue							Х	Х	Х			
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous, Directed, SIP						Х	Х	Х			
Skin												
Tendon												
Testicular Tissue							Х	Х	Х			
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3023813954 Legal Name: ReproTech LLC