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: 0001372065

Other FDA Registrations: Blood: FEI: 0001372065

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/28/2023 Summary Report Print Date: 12/01/2023

No

Legal Name and Location:

University of Roch-Strong Memorial Hospital

601 Elmwood Avenue

Box 608

Rochester, New York 14642-0001

USA

Phone: 585-275-3189

Reporting Official:

Neil Blumberg, Director Transfusion Medicine

601 Elmwood Avenue

Box 608

Rochester, New York 14642-0001

Phone: 585-275-3189 Ext. Neil_Blumberg@urmc.rochester.edu Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:

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												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis	Autologous, Family Related	х	Х		Х	х	Х	Х	Х			
HPC Cord Blood										28-DEC-18		
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid		х	Х		Х	х	Х	Х	Х			
Pericardium												
Peripheral Blood Mononuclear Cells	Autologous, Family Related	х	Х		Х	х	Х	Х	Х			
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FEI:

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 0001372065 Legal Name: University of Roch-Strong Memorial Hospital