## 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: 0001875548

Other FDA Registrations: Blood: FEI: 0001875548

Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024
Last Registration Receipt Date: 11/15/2023
Summary Report Print Date: 12/01/2023

Legal Name and Location:

Grand Rapids, Michigan 49503-1704

Versiti Michigan, Inc 1036 Fuller Avenue NE

Phone: 616-233-8557

USA

Reporting Official:

Dana Knight, Director, Quality Assurance

1036 Fuller Avenue NE

Grand Rapids, Michigan 49503-1704

USA

Phone: 708-359-2058 Ext.

versitiregulatoryaffairs@versiti.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)).

No

					Establishn	nent Function	ons					
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												
Fascia												
Heart Valve												
HPC Apheresis	Autologous, Family Related	х	Х		Х	Х	Х	Х	Х			
HPC Cord Blood	Family Related	Х	Х		Х	Х	Х	Х	Х			
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells	Family Related	Х	Х		Х	Х	Х	Х	Х			
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	Also unrelated allogeneic for HPC and Peripheral Blood Mononuclear Ce	ells

Proprietary Name(s):

FEI: 0001875548 Legal Name: Versiti Michigan, Inc