

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: 0001873403		Other FDA Registrations: Blood: FEI: 0001873403 Devices: Drugs:		Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/12/2024 Summary Report Print Date: 12/20/2024						
Legal Name and Location: Versiti Indiana, Inc 3450 N. Meridian Street Indianapolis, Indiana 46208 USA Phone: 317-916-5170 Ext.:		Reporting Official: Megan McShea, Manager, Regulatory 3450 N. Meridian Street Indianapolis, Indiana 46208 USA Phone: 317-916-5070 Ext. versitiregulatoryaffairs@versiti.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)).						
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				X								
Blood Vessel				X								
Bone				X								
Cardiac Tissue - non-valved				X								
Cartilage				X								
Cornea				X								
Dura Mater												
Embryo												
Fascia				X								
Heart Valve				X								
HPC Apheresis	Autologous, Family Related			X							15-NOV-18	
HPC Cord Blood	Autologous, Family Related			X								
Ligament				X								
Nerve Tissue												
Oocyte	Anonymous, Directed, SIP			X								
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid						X	X	X	X			
Pericardium				X								
Peripheral Blood Mononuclear Cells										31-DEC-23		
Peritoneal Membrane												
Sclera				X								
Semen	Directed, SIP			X			X					
Skin				X								
Tendon				X								
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue				X								

Additional Information: Testing for PBMCs and HPC Apheresis was never discontinued.

Proprietary Name(s):

FEI: 0001873403 Legal Name: Versiti Indiana, Inc