


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: Change In Information Last Annual Registration Year: 2022 Last Registration Receipt Date: 01/04/2022 Summary Report Print Date: 01/05/2022
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Legal Name and Location: Versiti Indiana, Inc 3450 N. Meridian Street Indianapolis, Indiana 46208 USA Phone: 317-916-5170 Ext.:	Reporting Official: Rebecca L Moss, Quality Assurance Principal 3450 N. Meridian Street Indianapolis, Indiana 46208 USA Phone: 317-916-5179 Ext. bmoss@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)).
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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				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	Autologous, Family Related			X							15-NOV-18	
Peritoneal Membrane												
Sclera				X								
Semen	Directed, SIP			X			X					
Skin				X								
Tendon				X								
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue				X								

Additional Information: Versiti Indiana, INC does collect and send for further manufacturing apheresis collections from late stage prostate cancer patients for Provenge. This was previously listed as Somatic cell therapy products but that category is no longer available. Testing for PBMCs and HPC Apheresis was never discontinued.

Proprietary Name(s):

FET: 0001873403

Legal Name:

Versiti Indiana, Inc