## 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: 3002930204

Other FDA Registrations: Blood: FEI: 0002171378

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 Wisconsin, Inc. 638 N. 18th Street

Reporting Official:

Megan McShea, Manager, Regulatory

3450 N Meridian St

Indianapolis, Indiana 46208

Phone: 317-916-5070 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

No

1271.27(b)).

Milwaukee, Wisconsin 53233-2121

USA

Phone: 800-722-8230

Ext.:

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

Additional Information:	No additional information provided.
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Proprietary Name(s):

FEI: 3002930204 Legal Name: Versiti Wisconsin, Inc.