DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

Ext.:

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

Legal Name and Location:

Milwaukee, Wisconsin 53233-2121

Versiti Wisconsin, Inc. 638 N. 18th Street

Phone: 800-722-8230

USA

Reporting Official:

Dana Knight, Director, Quality Assurance

638 N. 18th Street

Milwaukee, Wisconsin 53233-2121

Phone: 708-359-2058 Ext. versitiregulatoryaffairs@versiti.org Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only:

No

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)).

Establishment Functions Date of Date of Proprietary Name(s) HCT/P(s) Donor Type(s) Screen Donor Testina Package Process Store Label Distribute Discontinuance Resumption Х Amniotic Membrane Χ Blood Vessel Х Χ Χ Χ Bone Cardiac Tissue - non-valved Cartilage Χ Χ Х Cornea Dura Mater Embryo Fascia Χ Χ Heart Valve Х Χ **HPC Apheresis** HPC Cord Blood Χ Х Ligament Nerve Tissue Oocyte Ovarian Tissue Pancreatic Islet Cells - autologous Parathyroid Pericardium Х Χ Peripheral Blood Mononuclear Cells Peritoneal Membrane Sclera Semen Skin Х Χ Tendon Х Х Testicular Tissue Tooth Pulp Χ Х **Umbilical Cord Tissue**

Additional Information:	No additional information provided.
	p

Proprietary Name(s):

FEI: 3002930204 Legal Name: Versiti Wisconsin, Inc.