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: 0001873403

Other FDA Registrations: Blood: FEI: 0001873403

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:

Indianapolis, Indiana 46208

Phone: 317-916-5170

Versiti Indiana, Inc 3450 N. Meridian Street

USA

Tendon

Testicular Tissue
Tooth Pulp

Umbilical Cord Tissue

Reporting Official:

Dana Knight, Director, Quality Assurance

3450 N. Meridian Street Indianapolis, Indiana 46208

LISA

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

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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

Establishment Functions Date of Date of Proprietary Name(s) Donor Type(s) HCT/P(s) Screen Donor Testina Package Process Store Label Distribute Discontinuance Resumption Amniotic Membrane Χ Blood Vessel Χ Χ Bone Cardiac Tissue - non-valved Х Cartilage Χ Х Cornea Dura Mater Embryo Fascia Х Heart Valve Х Χ **HPC Apheresis** Autologous, Family Related 15-NOV-18 HPC Cord Blood Autologous, Family Related Х Х Ligament Nerve Tissue Oocyte Anonymous, Directed, SIP Χ Ovarian Tissue Pancreatic Islet Cells - autologous Χ Parathyroid Х Χ Χ Pericardium Χ Peripheral Blood Mononuclear Cells Autologous, Family Related Χ 15-NOV-18 Peritoneal Membrane Χ Sclera Semen Directed, SIP Х Х Skin Χ

Additional information: Lesting for PBIMCs and HPC Apheresis was never discontinue	Additional Information:	Testing for PBMCs and HPC Apheresis was never discontinued.
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Proprietary Name(s):

FEI: 0001873403 Legal Name: Versiti Indiana, Inc