

FEI: 0001873403

Other FDA Registrations:
Blood: FEI: 0001873403
Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing
 Last Annual Registration Year: 2023
 Last Registration Receipt Date: 11/29/2022
 Summary Report Print Date: 12/01/2022

Legal Name and Location:

Versiti Indiana, Inc
 3450 N. Meridian Street

Indianapolis, Indiana 46208
 USA

Phone: 317-916-5170

Ext.:

Reporting Official:

Dana Knight, Director, Quality Assurance
 3450 N. Meridian Street
 Indianapolis, Indiana 46208
 USA
 Phone: 708-359-2058 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 | 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):

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Legal Name:

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