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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,<br/>         TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS<br/>         DESCRIBED IN 21 CFR 1271.10</b> | <b>FEI:</b> 0002171378 | <b>Other FDA Registrations:</b><br><b>Blood:</b> FEI: 0002171378<br><b>Devices:</b><br><b>Drugs:</b> | Reason For Last Submission: Annual Registration/Listing<br>Last Annual Registration Year: 2024<br>Last Registration Receipt Date: 11/15/2023<br>Summary Report Print Date: 12/01/2023 |
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| <b>Legal Name and Location:</b><br><br>Versiti Wisconsin, Inc.<br>638 N. 18th Street<br><br>Milwaukee, Wisconsin 53233-2121<br>USA<br><br>Phone: 708-359-2058 <b>Ext.:</b> | <b>Reporting Official:</b><br>Dana Knight, Director, Quality Assurance<br>638 N. 18th Street<br>P.O. Box 2178<br>Milwaukee, Wisconsin 53201-2178<br>USA<br>Phone: 708-359-2058 Ext.<br>versitiregulatoryaffairs@versiti.org | <b>Satellite Recovery Establishment:</b> No<br><b>Parent Manufacturing Establishment FEI No.:</b><br><b>Testing For Micro-Organisms Only:</b> No<br><br>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                   |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Blood Vessel                        |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Bone                                |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cardiac Tissue - non-valved         |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cartilage                           |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cornea                              |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Dura Mater                          |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Embryo                              |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Fascia                              |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Heart Valve                         |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| HPC Apheresis                       | Family Related | X                       |        |               | X       |         |       |       | X          |                        |                    |                     |
| HPC Cord Blood                      |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Ligament                            |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Nerve Tissue                        |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Oocyte                              |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Ovarian Tissue                      |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Pancreatic Islet Cells - autologous |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Parathyroid                         |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Pericardium                         |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Peripheral Blood Mononuclear Cells  | Family Related | X                       |        |               | X       |         |       |       | X          |                        |                    |                     |
| Peritoneal Membrane                 |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Sclera                              |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Semen                               |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Skin                                |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Tendon                              |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Testicular Tissue                   |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Tooth Pulp                          |                |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Umbilical Cord Tissue               |                |                         |        |               |         |         |       |       |            |                        |                    |                     |

**Additional Information:** No additional information provided.

**Proprietary Name(s):**

FEI: 0002171378

Legal Name:

Versiti Wisconsin, Inc.