

| | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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: 3009826876 | Other FDA Registrations: Blood: Devices: Drugs: | Reason For Last Submission: Change in Information Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/14/2022 Summary Report Print Date: 12/15/2022 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

| | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Legal Name and Location: DCI Donor Services dba Tennessee Donor Services (Nashville) 566 Mainstream Dr Suite 300 TN - Tennessee Nashville, Tennessee 37228 USA Phone: 615-564-3600 Ext.: | Reporting Official: Bronwyn Roberts, Quality and Compliance Manager 566 Mainstream Dr Suite 300 Nashville, Tennessee 37228 USA Phone: 615-564-3643 Ext. bronwyn.roberts@dcids.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 | X | | | | | | | | | |
| Blood Vessel | | X | X | | | | | | | | | |
| Bone | | X | X | | | | | | | | | |
| Cardiac Tissue - non-valved | | | | | | | | | | | | |
| Cartilage | | X | X | | | | | | | | | |
| Cornea | | X | X | | X | X | X | X | X | | | |
| Dura Mater | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | |
| Fascia | | X | X | | | | | | | | | |
| Heart Valve | | X | X | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | X | X | | | | | | | | | |
| Nerve Tissue | | X | X | | | | | | | | | |
| Oocyte | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | X | X | | | | | | | | | |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | X | X | | X | X | X | X | X | | | |
| Semen | | | | | | | | | | | | |
| Skin | | X | X | | | | X | | | | | |
| Tendon | | X | X | | | | | | | | | |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | X | X | | | | | | | | | |

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3009826876

Legal Name: DCI Donor Services dba Tennessee Donor Services (Nashville)