| 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: 3032593955 | | | Blood | Other FDA Registrations: Blood: FEI: 0001570984 Devices: Drugs: | | | | Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/21/2023 Summary Report Print Date: 10/08/2024 | | |
|---|---------------|---------|--|---------------|-----------------------|---------|--|-------|------------|--|---|---------------------|--|
| Legal Name and Location: Community Blood Center dba Solvita 349 S. Main Street Dayton, Ohio 45402-2715 USA Phone: 937-461-3450 Ext.: | | | Reporting Official: Christopher N Graham, President & CEO 349 S. Main Street Dayton, Ohio 45402-2715 USA Phone: 937-461-3413 Ext. pmalone@cbccts.org | | | | | | | Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: 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) | Recover | Screen | Donor Testing | Establishn Package | Process | Store | Label | Distribute | Date of Discontinuance | Date of Resumption | Proprietary Name(s) | |
| Amniotic Membrane | | x | x | | | | | | | | | | |
| Blood Vessel | | х | x | | | | | | | | | | |
| Bone | | x | х | | | | x | | | | | | |
| Cardiac Tissue - non-valved | | x | х | | | | | | | | | | |
| Cartilage | | x | х | | х | х | x | | | | | | |
| Cornea | | | х | | | | | | | | | | |
| Dura Mater | | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | | |
| Fascia | | x | х | | | | x | | | | | | |
| Heart Valve | | x | х | | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | | |
| Ligament | | x | х | | | | x | | | | | | |
| Nerve Tissue | | x | х | | | | | | | | | | |
| Oocyte | | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | | |
| Pericardium | | x | х | | | | x | | | | | | |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | | |
| Sclera | | | х | | | | | | | | | | |
| Semen | | | | | | | | | | | | | |
| Skin | | х | х | | х | х | x | | | | | | |
| Tendon | | Х | х | | | | x | | | | | | |
| Testicular Tissue | | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | | |

Legal Name:

Additional Information: HCT/P establishment registration previously was under FEI: 0001570984. New FEI: 3032593955 assigned by ORA on October 08, 2024.

Proprietary Name(s):

FEI: 3032593955

Legal Name:

Community Blood Center dba Solvita

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026