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: 3024790917

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Change in Information

Last Annual Registration Year: 2024 Last Registration Receipt Date: 02/13/2024 Summary Report Print Date: 04/19/2024

No

Legal Name and Location:

Community Blood Center dba Solvita 18111 NE Sandy Blvd

Reporting Official: Christopher N Graham, President & CEO

349 South Main Street

Dayton, Ohio 45402-2715

Phone: 937-461-3413 Ext. pmalone@cbccts.org

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)).

Portland, Oregon 97230

USA

Phone: 503-408-9394

Ext.:

| | Donor Type(s) | Establishment Functions | | | | | | | | | | |
|-------------------------------------|---------------|-------------------------|--------|---------------|---------|---------|-------|-------|------------|------------------------|-----------------------|------------------------|
| HCT/P(s) | | Recover | Screen | Donor Testing | Package | Process | Store | Label | Distribute | Date of Discontinuance | Date of Resumption | Proprietary Name(s) |
| Amniotic Membrane | | | | | | | | | | | | |
| Blood Vessel | | X | Х | | | | Х | | Х | | | AngioGraft |
| Bone | | X | Х | | | | Х | | Х | | | Maxxeus |
| Cardiac Tissue - non-valved | | X | Х | | | | | | | | | |
| Cartilage | | X | Х | | | | Х | | Х | | | Maxxeus |
| Cornea | | | | | | | | | | | | |
| Dura Mater | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | |
| Fascia | | X | Х | | | | Х | | Х | | | Maxxeus |
| Heart Valve | | X | Х | | | | Х | | Х | | | CardioGraft, CryoValve |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | X | Х | | | | Х | | X | | | Maxxeus |
| Nerve Tissue | | X | Х | | | | | | | | | |
| Oocyte | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | Х | Х | | | | Х | | Х | | | Maxxeus |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | | | | | | | | | | | |
| Semen | | | | | | | | | | | | |
| Skin | | Х | Х | | | | Х | | Х | | | Maxxeus |
| Tendon | | Х | Х | | | | Х | | Х | | | Maxxeus |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | |

| Additional Information: | No additional information provided |
|-------------------------|------------------------------------|
| | |

Proprietary Name(s):

FEI: 3024790917 Legal Name: Community Blood Center dba Solvita