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

Ext.:

FEI: 3008808182

Other FDA Registrations: Blood:

Devices: Drugs: Reason For Last Submission: Change in Information

Last Annual Registration Year: 2023
Last Registration Receipt Date: 07/24/2023
Summary Report Print Date: 09/11/2023

No

Legal Name and Location:

Community Blood Center dba Solvita

2900 College Drive

Kettering, Ohio 45420

USA

Phone: 937-461-3450

Reporting Official:

Christopher N Graham, 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)).

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

Additional Information:	Proprietary Names - Maxxeus, DermaPure, Bio4, Cartiform, CREOS Allogain, Glenojet, SpeedSpiral, SpiralUp, BioXclude, Osteoamp, Preserve, Avitrac, Unite, OsteoSource Allosorb, Osteostim, Valoross, Evologics, Parametrics, Duet, NMP

Proprietary Name(s):

FEI: 3008808182 Legal Name: Community Blood Center dba Solvita