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: 3024790917

Other FDA Registrations: Blood:

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: 01/05/2024

No

Legal Name and Location:

Portland, Oregon 97230

Phone: 503-408-9394

USA

Community Blood Center dba Solvita 18111 NE Sandy Blvd Christopher N Graham, President & CEO 349 South Main Street

Dayton, Ohio 45402-2715

USA

Phone: 937-461-3413 Ext.

pmalone@cbccts.org

Reporting Official:

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												
Blood Vessel		Х	Х				Х		Х			
Bone		Х	Х				Х		Х			
Cardiac Tissue - non-valved		Х	Х									
Cartilage		Х	Х				Х		Х			
Cornea												
Dura Mater												
Embryo												
Fascia		X	Х				Х		Х			
Heart Valve		X	Х				Х		Х			
HPC Apheresis												
HPC Cord Blood												
Ligament		Х	Х				Х		Х			
Nerve Tissue		X	Х				Х		Х			
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		Х	Х				Х		Х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin		Х	Х				Х		Х			
Tendon		Х	Х				Х		Х			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Pr	roprietary Name - Maxxeus, Axogen, Cryolife/Artivion
----------------------------	--

Proprietary Name(s):

FEI: 3024790917 Legal Name: Community Blood Center dba Solvita