## 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: 3008808182

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Change in Information

Last Annual Registration Year: 2024 Last Registration Receipt Date: 01/02/2024 Summary Report Print Date: 01/05/2024

Legal Name and Location:

Community Blood Center dba Solvita

2900 College Drive

Kettering, Ohio 45420

USA

Phone: 937-461-3450

Ext.:

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)).

No

	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					Х	Х	х	Х	Х	BioXclude		
Blood Vessel												
Bone					Х	Х	Х	Х	Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage					Х	Х	Х	Х	Х			Cartiform, Maxxeus
Cornea												
Dura Mater												
Embryo												
Fascia					X	х	Х	Х	Х			Maxxeus
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament					X	X	Х	Х	Х			Maxxeus
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium					Х	X	Х	Х	Х			Maxxeus
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					Х	х	Х	Х	Х			***See full text on next page.
Tendon					Х	х	Х	Х	Х			Maxxeus
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information	n: No additional information provided.	
Proprietary Name(s):	Bone	Maxxeus, Bio4, Creos Allogain, Glenojet, Osteoamp, Preserve, Avitrac, Unite, OsteoSource, AlloSorb, NMP, RegenerOss, AlloSync
-	Skin	Maxxeus, SpeedSpiral, Spiral Up

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