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: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/03/2024 Summary Report Print Date: 12/05/2024

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, President & CEO

349 South Main Street Dayton, Ohio 45402-2715

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

Satellite Recovery Establishment:

No

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)).

	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, Maxxeus
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					Х	х	Х	Х	Х			***See full text on next page.
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium					х	х	Х	Х	Х			***See full text on next page.
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					Х	х	Х	Х	Х			Maxxeus, SpeedSpiral, SpiralUp
Tendon					Х	х	Х	Х	Х			***See full text on next page.
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

roprietary Name(s):	Bone	PrecisionGraft, Centerpiece, Triad, Capstone, Raptos, Allosorb, Osteokor, Oragen, SpinalGraft, creos allo.gain, PRESERVE, RegenerOss, PrimaGen Advanced, OsteoSource, Bio4, Osteoamp, FlowerGraft, EvoGraft, AlloSync, Bonus Triad, PSIF, Glenojet, Unite, CornerLoc, Isotis, NMP, AlloBind DBM Crunch Putty, AlloBind DBM Putty, Shark Screw, Maxxeus	
	Ligament	Coll-e-Strong, Lo-RAD, No-RAD, Maxxeus	
	Ligament	Coll-e-Strong, Lo-RAD, No-RAD, Maxxeus	

Additional Information:

No additional information provided.

Pericardium

Tendon

Osteokor, creos allo.protect, Oragen, Maxxeus

Coll-e-Strong, Lo-RAD, SpeedGraft, VersaGraft, GraftLink, No-RAD, Maxxeus, EvoGraft