

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: 02/08/2024 Summary Report Print Date: 04/19/2024
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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 USA 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane					X	X	X	X	X			BioXclude, Maxxeus
Blood Vessel												
Bone					X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage					X	X	X	X	X			Cartiform, Maxxeus
Cornea												
Dura Mater												
Embryo												
Fascia					X	X	X	X	X			Maxxeus
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament					X	X	X	X	X			***See full text on next page.
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium					X	X	X	X	X			***See full text on next page.
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					X	X	X	X	X			Maxxeus, SpeedSpiral, SpiralUp
Tendon					X	X	X	X	X			***See full text on next page.
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary 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
Pericardium	Osteokor, creos allo.protect, Oragen, Maxxeus
Tendon	Coll-e-Strong, Lo-RAD, SpeedGraft, VersaGraft, GraftLink, No-RAD, Maxxeus, EvoGraft

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