## 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: 2021 Last Registration Receipt Date: 12/16/2020 Summary Report Print Date: 12/28/2020

Legal Name and Location:

Community Blood Center dba Community Tissue Services

2900 College Drive

USA

Kettering, Ohio 45420

Phone: 937-461-3450

Reporting Official:

David M Smith. 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)).

		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			
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					Х	Х	Х	Х	Х			

Additional Information: Proprietary Names - Maxxeus, DermaPure, Stravix, Bio4, Cartiform, CREOS Allogain, Glenojet, SpeedSpiral, SpiralUp, BioXclu	Additional Information:	Proprietary Names - Maxxeus, DermaPure, Stravix, Bio4, Cartiform, CREOS Allogain, Glenojet, SpeedSpiral, SpiralUp, BioXclud
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Proprietary Name(s):

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