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#### **eHCTERS - Registration Information**

### **Submitted Registration Information**

This information has been submitted to the FDA
Please Remember Your Confirmation Number to Reference this registration submission
YOUR CONFIRMATION NUMBER IS: 61704

Please print this document and maintain as confirmation of your submission. This application is no longer accessible using your pre-confirmation number.

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	FEI: 3	3024790917			
Other FDA Registrations		Reason for Subi	mission		
Blood	☐ Initial Registration/Listing				
Devices		_	istration/Listing		
Drug		☑ Change in I			
	☐ In-Activate Registration				
Physical Location			. tog.ou.cu.o		
	Community Blood Cente	or dha Salvita			
_	= '	ei uba Soivita			
	18111 NE Sandy Blvd Portland				
•	Oregon				
Postal Code:	_				
	: UNITED STATES				
•	503-408-9394 ext.				
Reporting Official Information					
	Christopher N				
	Christopher N. Graham MBA				
Title:					
	937-461-3413 Ext.				
	pmalone@cbccts.org				
Mailing Address of Reporting C					
	Community Blood Cente	er dba Solvita			
	349 South Main Street				
City:	: Dayton				
State:	: Ohio				
Postal Code:	45402-2715				
Country:	UNITED STATES				
HCT/P Listing Information					
	HCT/Ps	Date of	Date of		
Types of HCT/Ps	Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Resumption (mm/dd/yyyy)	Proprietary Names	
Amniotic Membrane	X				
Blood Vessel	X				
Bone	X				
Cardiac Tissue - non-valved	X				

Χ

Cartilage

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

# HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane	$\overline{\mathbf{V}}$	$\overline{\mathbf{V}}$						
Blood Vessel	V	V				V		V
Bone	€	V				V		<b>√</b>
Cardiac Tissue - non-valved	€	V						
Cartilage	$\overline{ullet}$	$\overline{\mathbf{V}}$				V		$\overline{\mathbf{V}}$
Cornea								
Dura Mater								
Embryo								
Fascia	€	ے				V		€
Heart Valve	<b>√</b>	$\overline{\mathbf{V}}$				ے		lacksquare
HPC Apheresis								
HPC Cord Blood								
Ligament	€	<b></b> ✓				V		€
Nerve Tissue	<b>√</b>	$\overline{\mathbf{V}}$				ے		lacksquare
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium	€	ے				V		€
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin	lacksquare	$\mathbf{V}$				V		lacksquare
Tendon	$\overline{\mathbf{V}}$	<b>√</b>				ے		€
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue								

# HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

#### Additional Information

Proprietary Name - Maxxeus, Axogen, Cryolife/Artivion

Select New Establishment CBER On-Line Main Menu

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

> eHCTERS v02.13.01 Updated 11/20/2020

FDA information collection OMB Control number: 0910-0543 Expiration Date: 08/31/2026

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