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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: 61706

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

i nis applic	ation is no longer access	sible using your pre-d	confirmation numbe	er.		
	FEI: 3	3000718784				
Street Address:	Community Blood Cente 2736 N. Holland-Sylvani	Reason for Subrace Initial Regis Initial Regis Annual Reg Change in I In-Activate I	tration/Listing istration/Listing			
State: Postal Code: Country:						
Reporting Official Information First Name: Last Name: Last Name: Phone: E-Mail Address: Mailing Address of Reporting Official Institution Name: Street Address: City: State: Postal Code:	Christopher N. Graham MBA CEO 937-461-3413 Ext. pmalone@cbccts.org Official Community Blood Center 349 South Main Street Dayton Ohio 45402-2715	er dba Solvita				
Country: UNITED STATES						
HCT/P Listing Information						
Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Date of Discontinuance (mm/dd/yyyy)	Date of Resumption (mm/dd/yyyy)	Proprietary Names		
Amniotic Membrane	Х					
Blood Vessel	X					
Bone	X					
Cardiac Tissue - non-valved	X					

Cornea	X		
Dura Mater			
Embryo			
Fascia	Χ		
Heart Valve	Χ		
HPC Apheresis			
HPC Cord Blood			
Ligament	Χ		
Nerve Tissue	Χ		
Oocyte			
Ovarian Tissue			
Pancreatic Islet Cells -			
autologous			
Parathyroid			
Pericardium	Χ		
Peripheral Blood Mononuclear Cells			
Peritoneal Membrane			
Sclera	Х		
Semen			
Skin	Χ		
Tendon	Χ		
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	√	$\overline{\mathbf{V}}$						
Blood Vessel	V	lacksquare						
Bone	₹	<u> </u>				V		V
Cardiac Tissue - non-valved	<u> </u>	<u>~</u>						
Cartilage	€	$\overline{\mathbf{V}}$				V		V
Cornea	<u> </u>	<u>~</u>						
Dura Mater								
Embryo								
Fascia	$\overline{\mathbf{V}}$	$\overline{\mathbf{V}}$				ے		lacksquare
Heart Valve	€	V						
HPC Apheresis								
HPC Cord Blood								
Ligament	$\overline{\mathbf{V}}$	$\overline{\mathbf{V}}$				ے		lacksquare
Nerve Tissue	V	V						
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium	$\overline{\mathbf{V}}$	\mathbf{V}				V		lacksquare
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera	€	 ✓						
Semen								
Skin	€	V				V		lacksquare
Tendon	▼	▼				√		<u></u>
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					

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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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