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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: 53345

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

FEI: 3012622594 Other FDA Registrations Reason for Submission ☐ Initial Registration/Listing Blood ☐ Annual Registration/Listing Devices **✓** Change in Information Drug ☐ In-Activate Registration **Physical Location** Legal Name: Harbinger Medical Group L.L.C dba Tides Medical Street Address: 605 Kaliste Saloom Road Suite H City: Lafayette State: Louisiana Postal Code: 70508 Country: UNITED STATES Phone: 443-613-2475 ext. Satellite Recovery Establishment: Yes Parent Manufacturing Establishment FEI No.: 3010125671 **Reporting Official Information** First Name: Benjamin Last Name: Kimball Title: VP Quality & Regulatory Affairs Phone: 337-326-0625 Ext. E-Mail Address: bkimball@tidesmedical.com **Mailing Address of Reporting Official** Institution Name: Tides Medical Street Address: 605 Kaliste Saloom Rd Suite H City: Lafayette State: Louisiana Postal Code: 70508 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	X	ļ	Artacent Connect, AmnioHeal Plus, Artacent Flex, Artacent Wound, Artacent Ocular, SteriMend, Red Arch, Amniovant- G
Blood Vessel			
Bone			
Cardiac Tissue - non-valved			
Cartilage			
Cornea			
Dura Mater			
Embryo			
Fascia			
Heart Valve			
HPC Apheresis			
HPC Cord Blood			
Ligament			
Nerve Tissue			
Oocyte			
Ovarian Tissue			
Pancreatic Islet Cells - autologous			
Parathyroid			
Pericardium			
Peripheral Blood Mononuclear Cells			
Peritoneal Membrane			
Sclera			
Semen			
Skin			
Tendon			
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	√	\blacksquare		\blacksquare	\blacksquare	√	\blacksquare	
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament								
Nerve Tissue								
Oocyte								
Ovarian Tissue								
Pancreatic Islet Cells - autologous								
Parathyroid								
Pericardium								
Peripheral Blood Mononuclear Cells								
Peritoneal Membrane								
Sclera								
Semen								
Skin								

Tendon				
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					

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 v02.13.00 Updated 11/20/2020

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