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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: 60760
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 This application is no longer accessible using your pre-confirmation number.

FEI: 3009838457

Other FDA Registrations

- Blood
- Devices
- Drug

Reason for Submission

- Initial Registration/Listing
- Annual Registration/Listing
- Change in Information
- In-Activate Registration

Physical Location

Legal Name: Stability Biologics, LLC
 Street Address: 1077 Central Parkway South
 Suite 500
 City: San Antonio
 State: Texas
 Postal Code: 78232
 Country: UNITED STATES
 Phone: 210-233-6733 ext.

Reporting Official Information

First Name: Terry
 Last Name: Hill
 Title: Chief Operating Officer /Tissue Bank Dir
 Phone: 210-424-7308 Ext.
 E-Mail Address: thill@stabilitybio.com

Mailing Address of Reporting Official

Institution Name: Stability Biologics, LLC
 Street Address: 1077 Central Parkway South
 Suite 500
 City: San Antonio
 State: Texas
 Postal Code: 78232
 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			AmnioCore, AmnioCore Surgical, AmnioCore Burn, AmnioCore OP, Amnio Tri-Core, Amnio Quad-Core, LimaCore,

				Amnio Tri-Core Surgical, Amnio Quad-Core Surgical, AmnioCore Pro, AmnioCore Pro+
Blood Vessel				
Bone	X			Physio Moldable, Physio Blend, H100 DBM Putty, H100 DBM Crush-Mix, BioSponge, ZVPro, ZVMax, Charlie 1, AlphaFuse, DeltaStrand, EchoSponge
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	X			InteguPly
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		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Blood Vessel								
Bone		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
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						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
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					

Additional Information

DeltaStrand, AlphaFuse, Charlie 1, EchoSponge, LimaCore added 10/7/2020 AmnioCore Burn added 10/30/2020 AmnioCore OP added 7/29/2021 AmnioCore Flow Lyophilized & ZipGraft removed 8/30/2021 AmnioCore Surgical added 10/25/2021 Amnio Tri-Core added 3/4/2022 Amnio Quad-Core added 3/4/2022 Amnio Tri-Core Surgical added 12/21/22 Amnio Quad-Core Surgical added 12/21/22 AmnioCore Pro added 3/29/23 AmnioCore Pro+ added 3/29/23

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: 07/31/2023

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