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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: 68026

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

	FEI: 301	1380649
Other FDA Registrations		Reason for Submission
☑ Blood 000	0068026	☐ Initial Registration/Listing
Devices		✓ Annual Registration/Listing
☐ Drug		☐ Change in Information
		☐ In-Activate Registration
Physical Location	a. a	
	StemCyte India Therape	
Street Address:	Apollo Hospital Campus,	PIOT NO TA.
	Bhat GIDC Estate	
City	Gujarat, India Gandhinagar	
Postal Code:		
Country:		
	7961701001 ext.	
Reporting Official Information	roomoroon oxu	
	BHAVIN B.	
	KAPADIYA DR.	
Title:	MEDICAL DIRECTOR	
Phone:		
E-Mail Address:		
Mailing Address of Reporting Off	icial	
Institution Name:	StemCyte India Therape	utics Pvt Ltd
Street Address:	Apollo Hospital Campus,	Plot No 1A.
	Bhat GIDC Estate	
	Gujarat, India	
•	Gandhinagar	
Postal Code:		
Country:	INDIA	
U.S. Agent Information 1		
First Name:		
Last Name:	Wang Dr.	
Phone: E-Mail Address:		
Mailing Address of U.S. Agent 1		
Organization Name:	StomCuto Inc	
•	13800 Live Oak Ave.	
Olicot Address.	Baldwin Park	
Citv:	Baldwin Park	
State:		

Postal Code: 91706

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				
Blood Vessel				
Bone				
Cardiac Tissue - non-valved				
Cartilage				
Cornea				
Dura Mater				
Embryo				
Fascia				
Heart Valve				
HPC Apheresis				
HPC Cord Blood	X			
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								
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea								
Dura Mater								
Embryo								
Fascia								
Heart Valve								
HPC Apheresis								
HPC Cord Blood	ے	\mathbf{V}	lacksquare	lacksquare	lacksquare	\blacksquare	\blacksquare	lacksquare
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				ے	ے
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 v02.13.04 Updated 07/29/2024

OMB Control Number 0910-0543; Expiration Date 08/31/2026 See OMB Burden Statement

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