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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: 68032

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

		FEI: 30116	80766	
DCVICCS	011680766 011680766]	Reason for Subm Initial Registr Annual Registr Change in In In-Activate R	ration/Listing stration/Listing formation
Physical Location				
Legal Name:	Novex Innov	vations		
Street Address:	101 N Ches	tnut Street		
	Suite 308			
City:	Winston-Sa	lem		
6.5)	North Caroli			
Postal Code:	27101			
Country:	UNITED ST	ATES		
Phone:	336-231-669	93 ext.		
Reporting Official Information				
First Name:	Brandi			
Last Name:	Shanahan			
Title:	Director of C	Quality		
Phone:	336-231-66	93 Ext.		
E-Mail Address:	bshanahan(@novexinnovatio	ns.com	
Mailing Address of Reporting C	Official			
Institution Name:	Novex Innov	vations		
Street Address:	101 N Ches	tnut Street		
	Suite 308			
City:	Winston-Sa	lem		
State:	North Caroli	ina		
Postal Code:	27101			
Country:	UNITED ST	ATES		
	НС	T/P Listing	Information)
Types of HCT/Ps	HCT/Ps Described	Date of	Date of	Proprietary Names

	in 21 CFR 1271.10	Discontinuance Resumpt (mm/dd/yyyy) (mm/dd/yy	
Amniotic Membrane	Х		Complete AA; Complete ACA; Complete FT; Complete SL; MLG Complete; MLG Complete Woundcare; DuoAmnion; Most; Singlay; Total
Blood Vessel			
Bone			
Cardiac Tissue - non-valved			
Cartilage			
Cornea			
Dura Mater			
Embryo			
Fascia			
Heart Valve			
HPC Apheresis			
HPC Cord Blood		3	
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	X		

HCT/P Listing - Function Information

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane		V		V	V	V	√ í	V
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	V	\mathbf{V}	√	V	V	$\overline{\mathbf{V}}$

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

Currently accredited by AATB

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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 v02.13.04 Updated 07/29/2024

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

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