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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: 80019**

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

FEI: 3011692533

#### 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: Surgenex, LLC  
 Street Address: 15444 N. 76th Street  
 Suite #110  
 City: Scottsdale  
 State: Arizona  
 Postal Code: 85260  
 Country: UNITED STATES  
 Phone: 877-880-1862 ext.

#### Reporting Official Information

First Name: Jackie  
 Last Name: Warn  
 Title: Chief Quality & Regulatory Officer  
 Phone: 877-880-1862 Ext.  
 E-Mail Address: jackie.warn@surgenex.com

#### Mailing Address of Reporting Official

Institution Name: Surgenex, LLC  
 Street Address: 15444 N. 76th Street  
 Suite #110  
 City: Scottsdale  
 State: Arizona  
 Postal Code: 85260  
 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			SurGraft, SurPatch, SurGraft XT, SurGraft AC, SurGraft ACA, SurGraft TL, SurSight, BioSport Amniotic Membrane,

					Advantage-A Amniotic Membrane, Esano-A, Esano AC, Esano ACA, Neomem Xac, SurGraft FT, NeoStim, NeoStim DL, NeoStim TL, AmnioPly, Acesso DL, Acesso, Acesso TL, Acesso AC, Acesso Trifaca, Lamellas, Lamellas XT, Biotivity A/C Plus, Reeva FT, ArdeoGraft, PelloGraft, RenoGraft, SanoGraft, VitoGraft, Apollo FT, NeoThelium FT, NeoThelium 4L, NeoThelium 4L+, AdvoGraft One, AdvoGraft Dual, Icon ACA, Summit AAA, Summit FX, Summit AC, Revive FT, Revive TL, RevoShield+
Blood Vessel					
Bone	X				
Cardiac Tissue - non-valved					
Cartilage	X				
Cornea					
Dura Mater					
Embryo					
Fascia	X				
Heart Valve					
HPC Apheresis					
HPC Cord Blood					
Ligament	X				
Nerve Tissue					
Oocyte					
Ovarian Tissue					
Pancreatic Islet Cells - autologous					
Parathyroid					
Pericardium					
Peripheral Blood Mononuclear Cells					
Peritoneal Membrane					
Sclera					
Semen					
Skin	X				
Tendon	X				
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		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
Blood Vessel				<input checked="" type="checkbox"/>				
Bone		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
Cardiac Tissue - non-valved				<input checked="" type="checkbox"/>				
Cartilage		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
Cornea								
Dura Mater								
Embryo								
Fascia		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
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	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>				
Testicular Tissue							
Tooth Pulp							
Umbilical Cord Tissue	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>			

### 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 v02.13.04  
Updated 07/29/2024

OMB Control Number 0910-0543; Expiration Date 08/31/2026  
See [OMB Burden Statement](#)

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