

[FDA Home Page](#) | [Contact eHCTERS Technical Support](#) | [Log Out](#)**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, Reeve 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"/>	<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		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Cornea								
Dura Mater								
Embryo								
Fascia		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Heart Valve								
HPC Apheresis								
HPC Cord Blood								
Ligament		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<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"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Tendon		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<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					

[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](#)

[Contact eHCTERS Technical Support](#) | [Help with filling out this form](#) | [Release Notes](#) | [Log Out](#)

[Contact CBER](#) | [Contact FDA](#) | [Privacy](#)  
[FDA Home Page](#) | [Accessibility](#) | [HHS Home Page](#) | [Vulnerability Disclosure Policy](#)

FDA / Center for Biologics Evaluation and Research