

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3011692533	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2026 Last Registration Receipt Date: 11/17/2025 Summary Report Print Date: 12/01/2025
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Legal Name and Location: Surgenex, LLC 15444 N. 76th Street Suite #110 Scottsdale, Arizona 85260 USA Phone: 877-880-1862 Ext.:	Reporting Official: Jackie Warn, Chief Quality & Regulatory Officer 15444 N. 76th Street Suite #110 Scottsdale, Arizona 85260 USA Phone: 877-880-1862 Ext. jackie.warn@surgenex.com	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane		X	X		X	X	X	X	X			***See full text on next page.
Blood Vessel												
Bone			X		X	X	X	X	X			
Cardiac Tissue - non-valved												
Cartilage			X		X	X	X	X	X			
Cornea												
Dura Mater												
Embryo												
Fascia			X		X	X	X	X	X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			X		X	X	X	X	X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X		X	X	X	X	X			
Tendon			X		X	X	X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue		X	X				X					

Additional Information: No additional information provided.

Proprietary Name(s):	Amniotic Membrane	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, Reevea 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+
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