

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: 3005340932	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/21/2023 Summary Report Print Date: 01/05/2024
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Legal Name and Location: Skye Biologics Holdings LLC (DBA Skye Orthobiologics LLC, DBA Human Regener. 2255 Campus Drive El Segundo, California 90245 USA Phone: 310-796-5680 Ext.:	Reporting Official: Nancy Baskharoun, Sr. QA Manager 2255 Campus Dr. El Segundo, California 90245 USA Phone: 424-297-0564 Ext. nbaskharoun@humantissue.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 additional information
Blood Vessel												
Bone							X		X			
Cardiac Tissue - non-valved												
Cartilage										01-JAN-18		
Cornea												
Dura Mater												
Embryo												
Fascia										01-JAN-18		
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									X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue		X	X		X	X	X	X	X			See additional information

Additional Information: PROPRIETARY NAMES:

AMNIOTIC MEMBRANE: ActiveBarrier 45, ActiveBarrier 200, OculoMatrix, VisiDisc, WoundEx, WoundEx Disc, RX Membrane, MX Membrane, NX Membrane, WoundFix, WoundPlus, WoundPlus X, E-Graft

UC TISSUE: ActiveBarrier 2000, RX Membrane 2000

UC CONNECTIVE TISSUE: ActiveMatrix, CryoMatrix, PX50, DX100, RX

Proprietary Name(s):

FEI: 3005340932

Legal Name: Skye Biologics Holdings LLC (DBA Skye Orthobiologics LLC, DBA Human Regenerative Technologies LLC)