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

Ext.:

FEI: 3008066433

Other FDA Registrations:

Blood: Devices: Drugs:

Establishment Functions

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024
Last Registration Receipt Date: 11/17/2023
Summary Report Print Date: 12/01/2023

Legal Name and Location:

Genesis Biologics, Inc. 16782 Von Karman Ave.

Suite 17

Irvine, California 92606

USA

Phone: 657-888-6243

Reporting Official:

Steven T Bee, Chief Executive Officer

16782 Von Karman Ave.

Suite 17

Irvine, California 92606

USA

Phone: 657-888-6243 Ext. info@genesisbiologics.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)).

					Establishment Functions							
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane							Х		Х			Genesis Amniotic Membrane
Blood Vessel												
Bone							Х		Х			
Cardiac Tissue - non-valved												
Cartilage							Х		Х			
Cornea												
Dura Mater												
Embryo												
Fascia							Х		Х			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							Х		Х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							Х		Х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							Х		Х			
Tendon							Х		Х			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information	provided.

Proprietary Name(s):

FEI: 3008066433 Legal Name: Genesis Biologics, Inc.