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: 3010664398

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2024
Last Registration Receipt Date: 12/20/2023
Summary Report Print Date: 01/05/2024

Legal Name and Location:

CorneaGen, LLC
850 Health Sciences Road
Suite 2020

Irvine, California 92617
USA

Phone: 949-854-0800 **Ext.:**

Reporting Official:

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Ste 300
Seattle, Washington 98101
USA
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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)).

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			***See full text on next page.
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea					X		X	X	X			VisionGraft
Dura Mater												
Embryo												
Fascia							X		X			TUTOPLAST
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					X		X	X	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

Additional Information: No additional information provided.

Proprietary Name(s):	Amniotic Membrane	AmnioGraft, PROKERA, Neox Flo, Clarix Flo, Neox 100, Clarix 100

FEI: 3010664398

Legal Name: CorneaGen, LLC