

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: 2022 Last Registration Receipt Date: 12/21/2021 Summary Report Print Date: 01/05/2022
--	------------------------	--	---

Legal Name and Location: CorneaGen 850 Health Sciences Road Suite 2020 Irvine, California 92617 USA Phone: 949-854-0800 Ext.:	Reporting Official: Thomas D Miller, VP of Quality and Regulatory Affairs 1200 6th Ave Ste 300 Seattle, Washington 98101 USA Phone: 206-838-4630 Ext. tom.miller@corneagen.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)).
---	--	--

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			
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												

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