

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: 2020  
 Last Registration Receipt Date: 12/03/2019  
 Summary Report Print Date: 12/10/2019

**Legal Name and Location:**

CorneaGen  
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 Suite 2020

Irvine, California 92617  
 USA

Phone: 949-854-0800

Ext.:

**Reporting Official:**

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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			
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							X					***See full text on next page.

**Additional Information:** No additional information provided.

<b>Proprietary Name(s):</b>	Amniotic Membrane	AmnioGraft, PROKERA, Neox Flo, Clarix Flo, Neox 100, Clarix 100
	Umbilical Cord Tissue	Neox Cord 1k, Neox Cord RT, Clarix Cord 1k

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