

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: 3015927085

**Other FDA Registrations:**

**Blood:**

**Devices:**

**Drugs:**

Reason For Last Submission: Annual Registration/Listing  
 Last Annual Registration Year: 2020  
 Last Registration Receipt Date: 12/05/2019  
 Summary Report Print Date: 12/10/2019

**Legal Name and Location:**

CorneaGen - Seattle  
 1200 6th Ave  
 Ste 300  
  
 Seattle, Washington 98101  
 USA  
 Phone: 206-701-5840      **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)).

**Establishment Functions**

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			AmnioGraft, PROKERA
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea					X	X	X	X	X			
Dura Mater												
Embryo												
Fascia												
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	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

**Proprietary Name(s):**

FEI: 3015927085

Legal Name:

CorneaGen - Seattle