

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: 3001236461

**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 - Baltimore / Medical Eye Bank of Maryland  
 5520 Research Park Drive  
 Suite 400

Baltimore, Maryland 21228  
 USA

Phone: 410-752-3800 **Ext.:**

**Reporting Official:**

Thomas D Miller, VP of Quality and Regulatory Affairs  
 1200 6th Ave  
 Suite 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                   |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Blood Vessel                        |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Bone                                |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cardiac Tissue - non-valved         |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cartilage                           |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Cornea                              |               |                         | X      |               | X       | X       | X     | X     | X          |                        |                    | VisionGraft         |
| 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          |                        |                    |                     |
| Semen                               |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Skin                                |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Tendon                              |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Testicular Tissue                   |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Tooth Pulp                          |               |                         |        |               |         |         |       |       |            |                        |                    |                     |
| Umbilical Cord Tissue               |               |                         |        |               |         |         |       |       |            |                        |                    |                     |

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

**Proprietary Name(s):**

FEI: 3001236461

Legal Name: CorneaGen - Baltimore / Medical Eye Bank of Maryland