

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: 3012085771

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing
 Last Annual Registration Year: 2020
 Last Registration Receipt Date: 12/28/2019
 Summary Report Print Date: 01/07/2020

Legal Name and Location:

Axogen Corporation
 349 South Main Street
 4th Floor

Dayton, Ohio 45402
 USA

Phone: 386-462-6800

Ext.: 6820

Reporting Official:

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 mfriedman@axogeninc.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 | | | | | | | | | | | | |
| Dura Mater | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | |
| Fascia | | | | | | | | | | | | |
| Heart Valve | | | | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | | | | | | | | | | | |
| Nerve Tissue | | | | | X | X | X | X | | | | Avance |
| Oocyte | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | | | | | | | | | | | |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | | | | | | | | | | | |
| Semen | | | | | | | | | | | | |
| Skin | | | | | | | | | | | | |
| Tendon | | | | | | | | | | | | |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | X | X | X | X | | | | Avive |

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3012085771

Legal Name:

Axogen Corporation