

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: 3006252977

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing
 Last Annual Registration Year: 2021
 Last Registration Receipt Date: 11/16/2020
 Summary Report Print Date: 11/30/2020

Legal Name and Location:

AxoGen Corporation
 13631 Progress Blvd.
 Suite 400

Alachua, Florida 32615
 USA

Phone: 386-462-6800

Ext.: 6820

Reporting Official:

Mark L Friedman, VP of RA&QA
 13631 Progress Blvd.
 Suite 400
 Alachua, Florida 32615
 USA
 Phone: 386-462-6800 Ext. 6820
 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)).

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												
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		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		Avive

Additional Information: In response to COVID-19 Axogen plans to make its Alachua, FL office able to operate as a distribution center in the event it is needed to support maintenance of product supply to HCF.

Proprietary Name(s):

FEI: 3006252977

Legal Name:

AxoGen Corporation