## 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

Ext.: 6820

FEI: 3006252977

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/20/2023 Summary Report Print Date: 12/01/2023

No

Legal Name and Location:

AxoGen Corporation 13631 Progress Blvd. Suite 400

Alachua, Florida 32615

Phone: 386-462-6800

USA

Reporting Official:

Elizabeth Grover, Director Tissue Services QA

13631 Progress Blvd. Suite 400

Suite 400

Alachua, Florida 32615

USA

Phone: 386-462-6800 Ext. 6840

ra@axogeninc.com

Satellite Recovery Establishment:

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)).

	Donor Type(s)	Establishment Functions										
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane			Х									Avive+ Soft Tissue Matrix
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue			Х				Х		Х			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										01-JUN-21		