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.:

FEI: 3005897621

Reporting Official:

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2024
Last Registration Receipt Date: 06/18/2024
Summary Report Print Date: 06/28/2024

Legal Name and Location:

Marietta, Georgia 30062

Phone: 770-651-9209

USA

MiMedx Tissue Services, LLC 1775 West Oak Commons Court NE Rebeccah Brown, VP, Global Regulatory Affairs 1775 West Oak Commons Ct NE

Marietta, Georgia 30062

USA

Phone: 770-651-9123 Ext. rbrown@mimedx.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)).

	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	Х		Х	Х	Х	Х	Х			*** See full text on next page
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
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												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue		х	Х		Х	х	Х	Х	Х			*** See full text on next page

Additional Information:	Amniotic Membrane: AmnioBurn, AmnioEffect, AmnioFix, AmnioGenix, AmnioVantage, AxioFill, EpiBurn, EpiEffect, EpiFix, EpiXL, EpiXpress, OcuFix, Spectrix.
	Umbilical Cord: AmnioCord, AmnioVantage, EpiCord.

Proprietary Name(s):

FEI: 3005897621 Legal Name: MiMedx Tissue Services, LLC