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: 3016690655

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2024

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/28/2023 Summary Report Print Date: 12/01/2023

No

Legal Name and Location:

LeMaitre Vascular, Inc 2350 E. Germann Rd Suite 38 Timothy M Stevens, Director, Allografts, QA/RA 2350 E. Germann Rd Suite 38 Chandler, Arizona 85286

Reporting Official:

Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only:

Satellite Recovery Establishment:

Testing For Micro-Organisms Only: No

Chandler, Arizona 85286

USA

Phone: 480-590-4462 **Ext.:**

Phone: 224-500-0505 Ext. tstevens@lemaitre.com

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)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel							X		X			
Bone												
Cardiac Tissue - non-valved							Х		х			
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve							Х		Х			
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												

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3016690655 Legal Name: LeMaitre Vascular, Inc