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: 0001220948

Other FDA Registrations:
Blood:
Devices: FEI: 0001220948
Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2026
Last Registration Receipt Date: 08/26/2026
Summary Report Print Date: 10/16/2026

Legal Name and Location:

LeMaitre Vascular, Inc
53 Second Ave

Burlington, Massachusetts 01803
USA

Phone: 781-221-2266 **Ext.:**

Reporting Official:

Xiang Zhang, VP of Regulatory Affairs
32 Third Ave
Burlington, Massachusetts 01803
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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					X	X	X	X	X			
Bone												
Cardiac Tissue - non-valved					X	X	X	X	X			
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve					X	X	X	X	X			
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												

FDA information collection OMB Control number: 0910-0543, expiration date: 03/31/2027

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 0001220948

Legal Name: LeMaitre Vascular, Inc