## DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

## FOOD AND DRUG ADMINISTRATION MENT REGISTRATION AND LISTING FOR HUMA

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

Ext.:

FEI: 3010593108

Other FDA Registrations: Blood:

Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/02/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

LeMaitre Vascular, Inc 912 Northwest Highway

Suite 101

Fox River Grove, Illinois 60021

USA

Phone: 847-462-2191

Reporting Official:

Timothy M Stevens, Director, Allografts QA/RA

912 Northwest Highway

Suite 101

Fox River Grove, Illinois 60021

USA

Phone: 224-500-0505 Ext. tstevens@lemaitre.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												
Blood Vessel			X		Х	Х	Х	Х	Х			
Bone												
Cardiac Tissue - non-valved			Х		Х	Х	Х	Х	Х			
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve			х		Х	Х	Х	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: 3010593108 Legal Name: LeMaitre Vascular, Inc