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: 3000718321

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/25/2024

No

Legal Name and Location:

Eversight 3985 Research Park Drive

Ext.:

Ann Arbor, Michigan 48108 USA

Phone: 734-780-2100

Reporting Official:

Catherine McClory, Sr Director Compliance, QI and Training

3985 Research Park Drive Ann Arbor, Michigan 48108

Phone: 734-780-2601 Ext. cmcclory@eversightvision.org Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Summary Report Print Date: 12/05/2024

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)).

		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							Х		Х			
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		Х	Х		Х	х	Х	Х	Х			
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium										28-NOV-18		
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	Х		Х	Х	Х	Х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided
Additional information.	140 additional information provided.

Proprietary Name(s):

FEI: 3000718321 Legal Name: Eversight