## 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: 3013178553

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
Summary Report Print Date: 12/05/2024

No

Legal Name and Location:

Eversight Korea

Unit 202, 67, Gasan digital 2-ro

Geumcheon-gu

Seoul, 08588 KOREA, SOUTH

Phone: +82-2-2088-7003

Reporting Official:

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3985 Research Park Dr

Ann Arbor, Michigan 48108

USA

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

Satellite Recovery Establishment:

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)).

		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												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea					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												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera					X		Х	Х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

## For Non U.S. Establishments Only:

U.S. Agent(s):

Name and Organization	Address	Phone and Email		
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Eversight Michigan Importer(s):		cmcclory@eversightvision.org		
Name and Organization	Address	Phone and Email		

FEI: 3013178553 Legal Name: Eversight Korea