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

Ext.:

FEI: 3000718321

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022
Last Registration Receipt Date: 11/16/2021
Summary Report Print Date: 12/01/2021

No

Legal Name and Location:

Eversight

3985 Research Park Drive

Ann Arbor, Michigan 48108

USA

Phone: 734-780-2100

Reporting Official:

Catherine McClory, Director Compliance and QI

3985 Research Park Drive 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

					Establishr	nent Function	ons					
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	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 illionnation provided

FEI: 3000718321 Legal Name: Eversight

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

Ext.:

FEI: 3001451642

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022

Last Annual Registration Year: 2022 Last Registration Receipt Date: 11/16/2021 Summary Report Print Date: 12/01/2021

Legal Name and Location:

Eversight 924 West 19th Place Suite 350

USA

Chicago, Illinois 60608

Phone: 312-706-6750

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: No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

					Establishr	nent Function	ns					
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	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									Х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		x	Х		х	X	Х	Х	х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FEI: 3001451642 Legal Name: Eversight

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

Ext.:

FEI: 3000718787

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2022 Last Registration Receipt Date: 11/16/2021 Summary Report Print Date: 12/01/2021

Legal Name and Location:

Eversight

USA

6700 Euclid Ave., Suite 101

Cleveland, Ohio 44103

Phone: 216-706-4220

Reporting Official:

Catherine McClory, Director Compliance and QI

3985 Research Park Dr Ann Arbor, Michigan 48108

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

No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

					Establishr	nent Function	ons					
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	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		х			Х	Х	Х	х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.
,	Tro additional information provided.

FEI: 3000718787 Legal Name: Eversight

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

Ext.:

FEI: 3001236615

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022
Last Registration Receipt Date: 11/16/2021
Summary Report Print Date: 12/01/2021

No

Legal Name and Location:

Eversight

77 Brant Avenue, Suite 100

Clark, New Jersey 07066 USA

Phone: 732-382-3060

Reporting Official:

Catherine McClory, Director Compliance and QI

3985 Research Park Drive Ann Arbor, Michigan 48108

LISA

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

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

					Establishr	nent Function	ons					
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		X	Х		X	X	Х	Х	X			
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	Х	Х	х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided

FEI: 3001236615 Legal Name: Eversight

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

FEI: 3013178553

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2022

Last Annual Registration Year: 2022 Last Registration Receipt Date: 11/16/2021 Summary Report Print Date: 12/01/2021

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 Ext.:

Reporting Official:

Catherine McClory, Director Compliance and QI

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

					Establishn	nent Function	ons					
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					X		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					Х		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		
Catherine M. McClory, Director Compliance and QI	3985 Research Park Dr, Ann Arbor, Michigan, USA 48108	734-780-2601		
Eversight Michigan		cmcclory@eversightvision.org		
Importer(s):				
Name and Organization	Address	Phone and Email		

FEI: 3013178553 Legal Name: Eversight Korea