#### 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: 1000517466

Other FDA Registrations: Blood:

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

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/20/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

Rocky Mountain Lions Eye Bank

1675 Aurora Court El 2049

Aurora, Colorado 80045

USA

Phone: 720-848-3937

Reporting Official:

John Lohmeier, Executive Director

Mail Stop F751, El 2049 1675 Aurora Court Aurora, Colorado 80045

USA

Phone: 720-848-3937 Ext. jlohmeier@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

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												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	Х		X	Х	Х	Х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

### 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: 3011694463

Reporting Official:

Other FDA Registrations:

Blood: Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/20/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C John Lohmeier. Executive Director 1675 Aurora Court

Mail Stop F751, El 2049 Aurora, Colorado 80045

Phone: 720-848-3937 Ext. jlohmeier@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

Testing For Micro-Organisms Only:

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)).

Aurora, Colorado 80010

USA

Phone: 720-848-3937

Ext.:

Martician			Establishment Functions									
Blood Vessel   Bloo	HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Resumption	Proprietary Name(s)
Bone	Amniotic Membrane											
Cardiac Tissue - non-valved         Image of the company of the	Blood Vessel											
Carliage	Bone											
Comes	Cardiac Tissue - non-valved											
Duri Mater   Dur	Cartilage											
Embryo         Embryo         Image: Control of the con	Cornea		х	Х		X	X	Х	Х	Х		
Fascia         Fascia         Image: Control of the con	Dura Mater											
Heart Valve         Image: Complex of the complex	Embryo											
HPC Aphresis         Image: Cord Blood         Image: Cord Blood <t< td=""><td>Fascia</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></t<>	Fascia											
HPC Cord Blood	Heart Valve											
Ligament         Ligament         Image: Control of the	HPC Apheresis											
Nerve Tissue         Image: Cocyte         Image: Co	HPC Cord Blood											
Cocyte         Image: Cocyte of Co	Ligament											
Ovarian Tissue         Image: Cells - autologous         Image: Cells	Nerve Tissue											
Pancreatic Islet Cells - autologous         Image: Cells - autologous of the cells - autol	Oocyte											
Parathyroid         Image: Control of the properties	Ovarian Tissue											
Pericardium         Image: Collaboration of Collaboration o	Pancreatic Islet Cells - autologous											
Peripheral Blood Mononuclear Cells         Image: Cells of the periton of the p	Parathyroid											
Peritoneal Membrane         Image: Control of the	Pericardium											
Sclera         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X         X <td>Peripheral Blood Mononuclear Cells</td> <td></td>	Peripheral Blood Mononuclear Cells											
Semen         Semen <th< td=""><td>Peritoneal Membrane</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></th<>	Peritoneal Membrane											
Skin         Skin <th< td=""><td>Sclera</td><td></td><td>Х</td><td>Х</td><td></td><td>Х</td><td>х</td><td>Х</td><td>Х</td><td>Х</td><td></td><td></td></th<>	Sclera		Х	Х		Х	х	Х	Х	Х		
Tendon         Image: Control of the pulp         Image: Control of t	Semen											
Testicular Tissue Tooth Pulp Tooth Pulp	Skin											
Tooth Pulp	Tendon											
	Testicular Tissue											
Umbilical Cord Tissue	Tooth Pulp											
OTTO TIONS	Umbilical Cord Tissue											

Proprietary Name(s):

#### 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: 1000517466

Other FDA Registrations: Blood:

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

Last Annual Registration Year: 2024
Last Registration Receipt Date: 12/07/2023
Summary Report Print Date: 12/15/2023

Legal Name and Location:

Rocky Mountain Lions Eye Bank

1675 Aurora Court El 2049

Aurora, Colorado 80045

USA

Phone: 720-848-3937

Reporting Official:

Michelle Carlino, Quality Assurance Manager

Mail Stop F751, El 2049 1675 Aurora Court Aurora, Colorado 80045

USA

Phone: 720-848-3937 Ext. mcarlino@corneas.org

Satellite Recovery Establishment:

Yes

Parent Manufacturing Establishment FEI No.: 1000517466

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												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	Х		Х	Х	Х	Х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

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

Ext.:

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10 FEI: 3011694463

Other FDA Registrations: Blood:

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

Last Annual Registration Year: 2024
Last Registration Receipt Date: 12/07/2023
Summary Report Print Date: 12/15/2023

Legal Name and Location:

Aurora, Colorado 80010

Phone: 720-848-3937

USA

Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Mic 167 Ma

Michelle Carlino, Quality Assurance Manager 1675 Aurora Court

Mail Stop F751, El 2049 Aurora, Colorado 80045

Reporting Official:

USA

Phone: 720-848-3937 Ext. mcarlino@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

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	X	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	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

## 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: 3011694463

Reporting Official:

Other FDA Registrations:

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

Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/19/2022 Summary Report Print Date: 01/05/2023

Legal Name and Location:

Aurora, Colorado 80010

Phone: 720-848-3937

USA

Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C John Lohmeier, Executive Director 1675 Aurora Court Mail Stop F751, El 2049 Aurora, Colorado 80045

1101

Phone: 720-848-3937 Ext. jlohmeier@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

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												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	Х		Х	Х	Х	Х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

# 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: 1000517466

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/19/2022 Summary Report Print Date: 01/05/2023

Legal Name and Location:

Rocky Mountain Lions Eye Bank

1675 Aurora Court El 2049

Aurora, Colorado 80045

USA

Phone: 720-848-3937

Reporting Official:

John Lohmeier. Executive Director

Mail Stop F751, EI 2049 1675 Aurora Court Aurora, Colorado 80045

Phone: 720-848-3937 Ext. jlohmeier@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

Testing For Micro-Organisms Only:

					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												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	Х		Х	Х	Х	Х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

#### 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: 1000517466

Other FDA Registrations:

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

Last Annual Registration Year: 2022
Last Registration Receipt Date: 12/06/2021
Summary Report Print Date: 12/15/2021

Legal Name and Location:

Rocky Mountain Lions Eye Bank

1675 Aurora Court E12049

Aurora, Colorado 80045

USA

Phone: 720-848-3937 **Ext.:** 

Reporting Official:

Ashi Moore, Quality Assurance Manager

Mail Stop F751 1675 Aurora Court Aurora, Colorado 80045

USA

Phone: 720-848-3934 Ext. amoore@corneas.org

Satellite Recovery Establishment:

Testing For Micro-Organisms Only:

Yes

1000517466

Parent Manufacturing Establishment FEI No.:

No

FII0116. 720-646-3937	LAU.											
					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		Х	Х		X	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	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

#### 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: 3011694463

Reporting Official:

Other FDA Registrations: Blood:

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:

Aurora, Colorado 80010

Phone: 720-848-3945

USA

Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C

Ashi Moore, Quality Assurance Manager 1675 Aurora Court Mail Stop F751

Aurora, Colorado 80045

Devices:

Drugs:

Phone: 720-848-3934 Ext. amoore@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

Testing For Micro-Organisms Only:

					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		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												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		X	Х		Х	Х	Х	Х	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

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: 1000517466

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2021
Last Registration Receipt Date: 11/17/2020
Summary Report Print Date: 11/30/2020

Legal Name and Location:

Rocky Mountain Lions Eye Bank

1675 Aurora Court E12049

Aurora, Colorado 80045

USA

Phone: 720-848-3937

Reporting Official:

Luana Marvin, Quality Assurance Manager

Mail Stop F751 1675 Aurora Court Aurora, Colorado 80045

USA

Phone: 720-848-3934 Ext. Imarvin@corneas.org Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

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												
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.

Proprietary Name(s):

## FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,

Ext.:

TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS **DESCRIBED IN 21 CFR 1271.10** 

FEI: 3011694463

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2021 Last Registration Receipt Date: 11/17/2020 Summary Report Print Date: 11/30/2020

Legal Name and Location:

Rocky Mountain Lions Eye Bank

15201 East Moncrieff Place Suite C

Aurora, Colorado 80010

USA

Phone: 720-848-3945

Reporting Official:

Luana Marvin, Quality Assurance Manager

1675 Aurora Court Mail Stop F751 Aurora, Colorado 80045

Phone: 720-848-3934 Ext. Imarvin@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

Testing For Micro-Organisms Only:

					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												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	Х		х	х	Х	Х	Х			
Semen												
Skin								<u> </u>			_	
Tendon								<u> </u>			_	
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.

Proprietary Name(s):

#### 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: 1000517466

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2020
Last Registration Receipt Date: 11/20/2019
Summary Report Print Date: 12/10/2019

Legal Name and Location:

Rocky Mountain Lions Eye Bank

1675 Aurora Court E12049

Aurora, Colorado 80045

USA

Phone: 720-848-3937

Reporting Official:

Luana Marvin, Quality Assurance Manager

Mail Stop F751 1675 Aurora Court Aurora, Colorado 80045

USA

Phone: 720-848-3934 Ext. Imarvin@corneas.org Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000517466

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		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	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.

Proprietary Name(s):

## 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: 3011694463

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2020 Last Registration Receipt Date: 11/20/2019 Summary Report Print Date: 12/10/2019

Legal Name and Location:

Aurora, Colorado 80010

Phone: 720-848-3945

USA

Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Luana Marvin, Quality Assurance Manager 1675 Aurora Court

Mail Stop F751 Aurora, Colorado 80045

Reporting Official:

Phone: 720-848-3934 Ext. Imarvin@corneas.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.:

1000517466 Testing For Micro-Organisms Only:

Filone. 720-040-3943														
					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						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						
Semen														
Skin														
Tendon														
Testicular Tissue														
Tooth Pulp														
Umbilical Cord Tissue														

Additional Information:	No additional information provided.

Proprietary Name(s):

# 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: 1000517468

Other FDA Registrations: Blood: Devices:

Druge:

Reason For Last Submission. Annual Registration/Listing
Last Annual Registration Year: 2019
Last Registration Receipt Date: 12/11/2016
Summary Report Print Date: 12/19/2018

Legal Name and Location:

Rocky Mountain Liona Eye Bank 1675 Aurora Court E12049

Aurora, Colorado 80045

Phone 720-848-3937

Enta

Reporting Officials
Edmund Jacobs, Executive Director
Mel Stop F751
1675 Aurora Court
Aurora, Colorado 80045
USA
Phone: 720-848-3950 Ext.

ejacobs@comeas.org

Satellite Recovery Establishment:
Parent Manutacturing Establishment FEI No.:
Teeting For Micro-Organisms Only:

1000517455

Yes

No

	Donor Type(s)				Establishe	ment Functi	ens						
HCT/P(=)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)	
Amniotic Membrana			And the little										
Blood Vessal								1116				and the same of th	
Bons													
Cardar Tissue - non-velved			1					1					
Cartilage			1									and the second s	
Comea		X	×		X	×	х	×	X	1			
Dura Mater											-		
Embryo												The state of the s	
Fascia													
leart Valve													
HPC Apharasis													
HPC Cord Blood													
Ugament						-							
Nerve T saus													
Docyte													
Dvarian Tissue													
Pancrestic Islet Cells - autologous			1	1									
Parathyroid													
Pencardium								11 11 11 11		1 1			
Peripheral Blood Mononuclear Cells		1				100							
Pentoneal Membrane													
Sciern		×	x		X	ж	x	x	×				
Semen			12.2										
Sken				Legender			- 1		- P				
Tendon													
Testoular Tissue													
Tooth Pulp													
Umbikcal Cord Tissue													

Additional information: No additional information provided.

Proprietary Name(s):

#### 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

Other FDA Registrations:

Blood: Devices:

Reason For Last Submission. Annual Registration/Listing Last Annual Registration Year 2019 Last Registration Receipt Date 12/11/2018

Oruge:

Summary Report Print Date: 12/19/2018

Legal Name and Location:

Rocky Mountain Lions Eye Bank 15201 East Monored Place Suite C Reporting Official: Edmond Jacobs, Executive Director Mail Slop F751 1675 Aurora Court Aurora, Colorado 50045

FEI: 3011894483

Salekite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Yes 1000517466

Testing For Micro-Organisms Only:

Aurora Colorado 80010

Phone: 720-848-3945

Esta

USA Phone 729-848-3850 Est. gro assertos Badoquaje

Note: FDA acceptance of an establishment registration and HCT/P listing does not room their 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)).

<b>НСТР</b> {s}		1	,		Establishn	nest Function	<b>2113</b>					
	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniobic Membrane												
Blond Vesstri		į								and a second		
Bone												
Cambac Tissue - non-valved												
Carblage												
Comes						x		x	1			
Dura Meter		-								!		
Embrya										<u> </u>		
Fascia							i			<u> </u>		
Heart Valve		i									a and	
HPC Apheresis												
HPC Cord Blood												
Ugament												
Nerva Tinsue												
Docyte			i					-		1		
Ovanan Tissus												
Pancrestic Islet Cells - autologous												
Parastyroid		- I										
Pencardum												
Peripheral Blood Mononucinar Cella					]					1	[	
Peritunual Membrana		1						,				
Sclera						×		д		1		
Samon											- April - Apri	
Skin											9.9	
Tendon	-											
Testicular Tissue						7						provinces and the contract of the state of the contract of the
Tooth Pulp	and the second							i				
Umbical Cord Tissus											and the state of t	

Legal Name



Additional information: No additional information provided.

Proprietary Name(s):

See Instructions for OMB Statement. FORM APPROVED: OMB No.0910-0543. Expiration Date: 6/30/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P) (See reverse side for instructions)	5, TISSUES, 1)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 1000517466					2. REASON FOR SUBMISSION  a. INITIAL REGISTRATION / LISTING  b. X ANNUAL REGISTRATION / LISTING  c. CHANGE IN INFORMATION  d. INACTIVE						DISTRICT: D			
PART I - ESTABLISHMENT INFORMATION	PART II - PI	RODUCT INFO	RMATIC	ON		100							2225 2225			
3. OTHER FDA REGISTRATIONS	The second section is a second section of the second section of the second section is a second section of the section of the second section of the section of the second section of the section of	IMENT FUNCTIO			OF HO	T/Ps					252	557	X COX			
a. BLOOD FDA 2830 NO.			tablishr	nent Fu	nctions		2	HCT/Pa SCRIBED L1271.10	EAS	See 3	14. PROPRIETARY NAME(S)					
b. DEVICES FDA 2891 NO.	Types o	f HCT / Ps	Recover	Recover Screen	een Test	Package	Process	Store	Label	Distribute	7	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. NCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS			
c. DRUG FDA 2656 NO.													Ca .			
PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone															
Rocky Mountain Lions Eye Bank	b. Cartilage															
1675 Aurora Court E12049	c. Comea		X	X		X	X	X	X	X	X					
Aurora, Colorado 80045	d. Dura Mater															
a, PHONE 720-848-3937 EXT	e, Embryo	SIP Directed Anonymous														
SATELLITE RECOVERY ESTABLISHMENT     MANUFACTURING ESTABLISHMENT FEI NO	f. Fascia	-														
a TESTING FOR MICRO-ORGANISMS ONLY	g. Heart Valve															
5. ENTER CORRECTIONS TO ITEM 4	h, Ugament															
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i, Oocyte	SIP Directed Anonymous														
Rocky Mountain Lions Eye Bank Attn. Jaime Wasniewski	j. Pericardium															
Mail Stop F751 1675 Aurora Court	k. Peripheral Blood Stem	Autologous Family Related Allogeneic														
Aurora, Colorado 80045	I. Sciera	0000	X	X		X	X	X	X	x	x					
a. PHONE 720-848-3934 EXT	m. Semen	SIP Directed Anonymous														
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin															
	o. Somatic Cell Therapy Products	Autologous Family Related Allogeneic														
8, U.S. AGENT	p. Tendon															
	q. Umbilical Cord Blood	Autologous Family Related Allogeneic														
a. E-MAIL	r, Vascular Graft															
9. REPORTING OFFICIAL'S SIGNATURE	8.															
faire Wasniewsh	t.															
a. TYPED NAME Jaime Wasniewski b. E-MAIL jwasniewski@corneas.org	u,															
c TITLE Quality Assurance Manager d DATE 16-NOV-2017	v.					1										

See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543, Expiration Date: 6/30/2020

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE		1. REGISTRATION NUMBER (FDA Establishment Identifier)							TRATIO	N/LISTIN		VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:16-NOV-2017 DISTRICT: Deriver			
FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P) (See reverse side for instructions)		FEI: 30116	b. X ANNUAL REGISTRATION / LISTING. CHANGE IN INFORMATION d. INACTIVE						PRINTED BY FDA:27-JAN-2018						
PART I - ESTABLISHMENT INFORMATION	PART II - PR	RODUCT INFOR	RMATIC	ON							유류크	M.R.t	228°		
3. OTHER FDA REGISTRATIONS	10. ESTABLISH	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										유민국	200 E	5	
a. BLOOD FDA 2830 NO.		Estal					nent Fu	nctions			100	PER PER		14. PROPRIETARY NAME(S)	
b. DEVICES FDA 2891 NO.	Types of	pes of HCT/Ps	Recover	Screen	Test	l Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	11. HCT/Ps REQULATED AS DRUGS OR BIOLOGICAL DRUGS		
c. DRUG FDA 2656 NO.															
<ol> <li>PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)</li> </ol>	a. Bone														
Rocky Mountain Lions Eye Bank	b. Cartilage							ļ							
15201 East Moncrieff Place Suite C Aurora, Colorado 80010	c. Comea						X		х		X				
	d. Dura Mater														
a. PHONE 720-848-3945 EXT	e. Embryo	StP Directed Anonymous													
b. X SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 1000517466  TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia														
5. ENTER CORRECTIONS TO ITEM 4	g, Hearl Valve														
	h. Ligament														
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	SIP Directed Anonymous													
Rocky Mountain Lions Eye Bank	j. Pericardium														
Attn: Jaime Wasniewski Mail Stop F751 1675 Aurora Court	k, Peripheral Blood Stern	Autologous Family Related Allogeneic													
Aurora, Colorado 80045	1. Sclera						x		X		X				
a. PHONE 7208483934 EXT 7. ENTER CORRECTIONS TO ITEM 6	m. Semen	SIP Directed Anonymous													
t. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin														
	o. Somatic Cell Therapy Products	Autologous Family Related Allogeneic													
8. U.S. AGENT	p. Tendon														
	q. Umbilicat Cord Blood	Autologous Family Related Allogeneic													
a. E-MAIL	r. Vascular Graft														
9. REPORTING OFFICIAL'S SIGNATURE	S.		1												
friend Wasmenshi	t.														
a. TYPED NAME Jaime Wasniewskii	u.		1												
b. E-MAIL jwasniewski@corneas.org		<u> </u>											,		
c. TITLE Quality Assurance Manager d. DATE 16-NOV-2017	v.											1			