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		Х	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 <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):

FEI: 1000517466 Legal Name: Rocky Mountain Lions Eye Bank

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):

FEI: 1000517466 Legal Name: Rocky Mountain Lions Eye Bank

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:

Establishment Functions

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

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:

Parent Manufacturing Establishment FEI No.: 1000517466

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)).

Yes

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

Proprietary Name(s):

FEI: 1000517466 Legal Name: Rocky Mountain Lions Eye Bank

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		X	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):

FEI: 1000517466 Legal Name: Rocky Mountain Lions Eye Bank

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		X	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		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):

FEI: 1000517466 Legal Name: Rocky Mountain Lions Eye Bank

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

нст/[•]					Establishe	ment Functi	ens					
	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrana			-									
Blood Vessal								1116				
Bons												
Cardar Tissue - non-velved			1					1				
Cartilage												and the second s
Comea		X	X		X	×	×	×	X	1		
Dura Mater												
Embryo										1		
Fascia										1		
leart Valve												
HPC Apharasis												
HPC Cord Blood												
Ugament						-						
Nerve T saus												
Docyte												
Dvarian Tissue												
Pancrestic Islet Cells - autologous				1								
Parathyroid												
Pericardium			1					11111				
Peripheral Blood Mononuclear Cells		1	- 1			100						
Pentoneal Membrane												
Sciern		×	x		×	ж	x	x	X			ates as
Semen			1000									
Skin				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)).

, jul 5 A dan 185 dimension			,		Establishn	nezi Functk	PITS						
HCT/P(s) Doner Type	Doner Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)	
Amniobic Membrane					1,22000000								
Blond Vesstri													
Bone													
Cardiac Tissue - non-valved													
Carblage									1				
Comes						x		x	!				
Dura Meter										!			
Embrya										<u> </u>			
Fascia							i			<u> </u>			
Heart Valve											1		
HPC Apheresis											1		
HPC Cord Blood											1		
Ugament		1											
Nerva Tinsuo		1											
Docyte			i					-		1			
Ovanan Tissus													
Pancrestic Islet Cells - autologous													
Parathyroid		*											
Pencardum											100		
Peripheral Blood Mononuchar Cella		1								,			
Peritunual Membrana		ì					i			1	and the same of th		
Sciena						×		ж					
Samon											dea		
Skin											dy age of the state of the stat		
Tendon	-												
Testicular Tissue												propagation of the control of the co	
Tooth Pulp												aranamananan maranan sana ya ngangarian 16 di dininini iliahinini iliahini iliahini iliahini iliahini iliahini	
Umblical Cord Tissue										l i			

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. REGISTRATI (FDA Establishm	a. [X ANNL	AL REGIS JAŁ REG IGE IN IN	STRATIC ISTRATI	N/LISTIN ON/LISTI	NG DI	DISTRICT D.					
PART I - ESTABLISHMENT INFORMATION	PART II - PI	RODUCT INFO	100		5.63			983	E 22	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	IMENT FUNCTIO	T/Ps					252	557	X COX				
a. BLOOD FDA 2830 NO.			tablishr	nent Fu	nctions		2	ICRIBED	EAS.	ESES.	14. PROPRIETARY NAME(S)			
b. DEVICES FDA 2891 NO.	Types o	f HCT / Ps	Recover	Screen	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	Х			
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. Sclera		X	X		X	X	X	X	x	x			100
a. PHONE 720-848-3934 EXT	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin													
	e. 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. TYPEO NAME Jaime Wasniewski b. E-MAIL jwasniewski@corneas.org	u,													
c TITLE Quality Assurance Manager d DATE 16-NOV-2017	v.													

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	REGISTRATION NUMBER (FDA Establishment Identalier)					a. [AL REGIS	TRATIO	N/LISTIN		VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:16-NOV-2017 DISTRICT: Denver				
FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P) (See reverse side for instructions)							12.1	IGE IN IN		ON/LIST(I TION	PR	PRINTED BY FDA:27-JAN-2018				
PART I - ESTABLISHMENT INFORMATION	PART II - PR	d. INACTIVE 日本の														
3. OTHER FDA REGISTRATIONS	10. ESTABLISH	MENT FUNCTIO	NS AND	TYPES	OF HC	T/Ps					200 E	유민국	A POST			
a. BLOOD FDA 2830 NO.				1	Es	tablishn	nent Fu	nctions			100	PER PER	£853	14. PROPRIETARY NAME(S)		
b. DEVICES FDA 2891 NO.	Types of	HCT/Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REQULATED AS DRUGS OR BIOLOGICAL DRUGS			
c. DRUG FDA 2656 NO.																
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	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				