

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: 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:**

Yes

**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)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X	X	X	X	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	X		X	X	X	X	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** N/A

**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 <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,          TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS          DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3011694463	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	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
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<b>Legal Name and Location:</b>  Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C  Aurora, Colorado 80010 USA  Phone: 720-848-3945 <b>Ext.:</b>	<b>Reporting Official:</b> Ashi Moore, Quality Assurance Manager 1675 Aurora Court Mail Stop F751 Aurora, Colorado 80045 USA Phone: 720-848-3934 Ext. amoore@corneas.org	<b>Satellite Recovery Establishment:</b> Yes <b>Parent Manufacturing Establishment FEI No.:</b> 1000517466 <b>Testing For Micro-Organisms Only:</b> 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X	X	X	X	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	X		X	X	X	X	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** N/A

**Proprietary Name(s):**

**FEI:** 3011694463

**Legal Name:**

Rocky Mountain Lions Eye Bank

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 1000517466	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	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
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<b>Legal Name and Location:</b>  Rocky Mountain Lions Eye Bank 1675 Aurora Court E12049  Aurora, Colorado 80045 USA  Phone: 720-848-3937 <b>Ext.:</b>	<b>Reporting Official:</b> Luana Marvin, Quality Assurance Manager Mail Stop F751 1675 Aurora Court Aurora, Colorado 80045 USA Phone: 720-848-3934 Ext. lmarvin@corneas.org	<b>Satellite Recovery Establishment:</b> Yes <b>Parent Manufacturing Establishment FEI No.:</b> 1000517466 <b>Testing For Micro-Organisms Only:</b> 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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X	X	X	X	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	X		X	X	X	X	X			
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

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

**Ext.:**

**Reporting Official:**

Luana Marvin, Quality Assurance Manager  
 1675 Aurora Court  
 Mail Stop F751  
 Aurora, Colorado 80045  
 USA  
 Phone: 720-848-3934 Ext.  
 lmarvin@corneas.org

**Satellite Recovery Establishment:**

Yes

**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)).

**Establishment Functions**

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X	X	X	X	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	X		X	X	X	X	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

**Proprietary Name(s):**

FEI: 3011694463

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**

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

Ext.:

**Reporting Official:**

Luana Marvin, Quality Assurance Manager  
 Mail Stop F751  
 1675 Aurora Court  
 Aurora, Colorado 80045  
 USA  
 Phone: 720-848-3934 Ext.  
 lmarvin@corneas.org

**Satellite Recovery Establishment:**

Yes

**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)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X	X	X	X	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	X		X	X	X	X	X			
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

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: 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:**

Rocky Mountain Lions Eye Bank  
 15201 East Moncrieff Place Suite C

Aurora, Colorado 80010  
 USA

Phone: 720-848-3945

**Ext.:**

**Reporting Official:**

Luana Marvin, Quality Assurance Manager  
 1675 Aurora Court  
 Mail Stop F751  
 Aurora, Colorado 80045  
 USA  
 Phone: 720-848-3934 Ext.  
 lmarvin@corneas.org

**Satellite Recovery Establishment:**

Yes

**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)).

**Establishment Functions**

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea						X			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			X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

**Proprietary Name(s):**

FEI: 3011694463

Legal Name:

Rocky Mountain Lions Eye Bank

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
 FOOD AND DRUG ADMINISTRATION  
 PUBLIC HEALTH SERVICE  
 ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  
 TISSUES, AND CELLULAR AND TISSUE-DERIVED PRODUCTS  
 DESCRIBED IN 21 CFR 1271.10

FBI: 1000517468

Other FDA Registrations:  
 Blood:  
 Devices:  
 Drugs:

Reason For Last Submission: Annual Registration/Listing  
 Last Annual Registration Year: 2019  
 Last Registration Recptl Date: 12/11/2018  
 Summary Report Print Date: 12/18/2018

Legal Name and Location:

Rocky Mountain Lorna Eye Bank  
 1675 Aurora Court  
 E12048  
 Aurora, Colorado 80045  
 USA  
 Phone: 720-848-3937

Ext.:

Reporting Official:  
 Edmund Jacoby, Executive Director  
 1675 Aurora Court  
 Aurora, Colorado 80045  
 USA  
 Phone: 720-848-3950 Ext.  
 ejacob@cornea.org

Sole/Partial Reciprocity Establishment: Yes  
 Parent Manufacturing Establishment FBI No.: 1000517468  
 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)).

HCT/P(s)	Donor Type(s)	Establishment Functions							Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recovery	Screen	Donor Testing	Package	Process	Store	Label			
Amniotic Membrane											
Blood Vessel											
Bone											
Cardiac Tissue - non-valved											
Cartilage		X	X		X	X	X	X	X		
Cornea											
Dura Mater											
Embryo											
Fascia											
Heart Valve											
hPFC Adhesives											
hPFC Cord Blood											
Ligament											
Mera Tissue											
Oocyte											
Ovarian Tissue											
Parotid (Salivary Gland) - autologous											
Pericardium											
Peripheral Blood Mononuclear Cells											
Peritoneal Membrane											
Sclera		X	X		X	X	X	X	X		
Serum											
Skin											
Tendon											
Tendons/Tissue											
Tooth Pulp											
Umbilical Cord Tissue											

**Additional Information:** No additional information provided.  
**Proprietary Name(s):**

**FEI:** 1000517460

**FDA Information collection:** Q148 Control Number: 09110-0543 expiration date: 6/30/2020  
**Page:** 1 of 2

**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

FEI: 301169443

Other FDA Registrations:  
 Biologics:  
 Devices:  
 Drugs:

Reason For Last Submission Annual Registration/Listing  
 Last Annual Registration Year 2018  
 Last Registration Receipt Date 12/1/2018  
 Summary Report Print Date 12/18/2018

Legal Name and Location:

Rocky Mountain Lens Eye Bank  
 15201 East Hancock Place Suite C  
 Aurora, Colorado 80010  
 USA  
 Phone 720-448-3945

Reporting Office:  
 Edward Jacobs, Executive Director  
 Mail Stop F51  
 1875 Aurora Court  
 Aurora, Colorado 80045  
 USA  
 Phone 720-448-3501 Ext. 61  
 ejacobs@cdcr.state.or.us

Stable Recovery Establishment: Yes  
 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)).

HCT/P(s)	Donor Type(s)	Establishment Functions							Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label			
Artificial Membrane											
Blood Vessel											
Bone											
Cartilage - non-velvied											
Cartilage											
Cornea					X			X			
Dura Mater											
Embryo											
Fat(s)											
Heart Valve											
HPC Adiposa											
HPC Cord Blood											
Ligament											
Nerve Tissue											
Oocyte											
Ovarian Tissue											
Pancreatic Islet Cells - autologous											
Placental											
Pancreas											
Peripheral Blood Mononuclear Cells											
Peritoneal Membrane											
Sclera					X			X			
Semen											
Skin											
Tendon											
Testicular Tissue											
Tooth Pulp											
Unipolar Cord Tissue											

**Additional Information:** No additional information provided.  
**Proprietary Name(s):**

**FEI 3011884403**

**FDA Information Collection CHS Control number: 0310-0543, expiration date: 03/02/2020**  
**Page 2 of 2**

**Legal Name:**

**Rocky Mountain Lens 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 (HCT/PS)**  
 (See reverse side for instructions)

1. REGISTRATION NUMBER  
 (FDA Establishment Identifier)  
 FEI: 1000517466

2. REASON FOR SUBMISSION  
 a.  INITIAL REGISTRATION / LISTING  
 b.  ANNUAL REGISTRATION / LISTING  
 c.  CHANGE IN INFORMATION  
 d.  INACTIVE

VALIDATION - FOR FDA USE ONLY  
 VALIDATED BY FDA: 16-NOV-2017  
 DISTRICT: Denver  
 PRINTED BY FDA: 27-JAN-2018

**PART I - ESTABLISHMENT INFORMATION**

3. OTHER FDA REGISTRATIONS  
 a. BLOOD FDA 2830 NO. \_\_\_\_\_  
 b. DEVICES FDA 2891 NO. \_\_\_\_\_  
 c. DRUG FDA 2856 NO. \_\_\_\_\_

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, county, and post office code)  
 Rocky Mountain Lions Eye Bank  
 1675 Aurora Court  
 E12049  
 Aurora, Colorado 80045

a. PHONE 720-848-3937 EXT \_\_\_\_\_  
 b.  SATELLITE RECOVERY ESTABLISHMENT  
 MANUFACTURING ESTABLISHMENT FEI NO. \_\_\_\_\_  
 TESTING FOR MICRO-ORGANISMS ONLY  
 c. ENTER CORRECTIONS TO ITEM 4 \_\_\_\_\_

5. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, county, and post office code)  
 Rocky Mountain Lions Eye Bank  
 Attn: Jaime Wasniewski  
 Mail Stop F751  
 1675 Aurora Court  
 Aurora, Colorado 80045

a. PHONE 720-848-3934 EXT \_\_\_\_\_  
 b. PHONE \_\_\_\_\_  
 7. ENTER CORRECTIONS TO ITEM 6 \_\_\_\_\_

**8. U.S. AGENT**

a. E-MAIL  
 Jaime Wasniewski  
 a. REPORTING OFFICIAL'S SIGNATURE  
 a. TYPED NAME Jaime Wasniewski  
 b. E-MAIL jwasniewski@comcas.org  
 c. TITLE Quality Assurance Manager  
 d. DATE 16-NOV-2017

**PART II - PRODUCT INFORMATION**

Types of HCT / Ps	Establishment Functions					11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS MEDICAL DEVICES REGULATED AS	13. HCT/PS DRUGS OR BIOLOGICAL DRUGS REGULATED AS	14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process				
a. Bone									
b. Cartilage									
c. Cornea	X	X		X	X	X	X	X	X
d. Dura Mater									
e. Embryo									
f. Falcia									
g. Heart Valve									
h. Ligament									
i. Oocyte									
j. Pericardium									
k. Peripheral Blood Stem									
l. Sclera	X	X		X	X	X	X	X	X
m. Semen									
n. Skin									
o. Somatic Cell Therapy Products									
p. Tendon									
q. Umbilical Cord Blood									
r. Vascular Graft									
s.									
t.									
u.									
v.									

