

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: 2025 Last Registration Receipt Date: 11/20/2024 Summary Report Print Date: 12/05/2024
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Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3937 Ext.:	Reporting Official: John Lohmeier, Executive Director 1675 Aurora Court Mail Stop F751, EI 2049 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 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

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Legal Name and Location: Rocky Mountain Lions Eye Bank 1675 Aurora Court EI 2049 Aurora, Colorado 80045 USA Phone: 720-848-3937 Ext.:	Reporting Official: Michelle Carlino, Quality Assurance Manager Mail Stop F751, EI 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 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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Peritoneal Membrane												
Sclera		X	X		X	X	X	X	X			
Semen												
Skin												
Tendon												
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Tooth Pulp												
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Additional Information: N/A

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Peritoneal Membrane												
Sclera		X	X		X	X	X	X	X			
Semen												
Skin												
Tendon												
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Umbilical Cord Tissue												

Additional Information: N/A

Proprietary Name(s):

FEI: 3011694463

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Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3937 Ext.:	Reporting Official: John Lohmeier, Executive Director 1675 Aurora Court Mail Stop F751, EI 2049 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 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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Pericardium												
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Peritoneal Membrane												
Sclera		X	X		X	X	X	X	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
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Additional Information: N/A

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Sclera		X	X		X	X	X	X	X			
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Tooth Pulp												
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Additional Information: N/A

Proprietary Name(s):

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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)).
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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 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: 2022 Last Registration Receipt Date: 11/16/2021 Summary Report Print Date: 12/01/2021
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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: Ashi Moore, Quality Assurance Manager 1675 Aurora Court Mail Stop F751 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)).
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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
**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: 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

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)).

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Additional Information: No additional information provided.

Proprietary Name(s):

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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: 2021 Last Registration Receipt Date: 11/17/2020 Summary Report Print Date: 11/30/2020
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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)).
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Additional Information: No additional information provided.

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Tooth Pulp												
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Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3011694463

Legal Name:

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 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

FBI: 1000517468

Other FDA Registrations:
 Blood:
 Devices:
 Drugs:

Reason For Last Submission: Annual Registration/Listing
 Last Annual Registration Year: 2019
 Last Registration Receipt Date: 12/11/2018
 Summary Report Print Date: 12/10/2018

Legal Name and Location:
 Rocky Mountain Lions Eye Bank
 1675 Aurora Court
 E12048
 Aurora, Colorado 80045
 USA
 Phone: 720-848-3937

Reporting Official:
 Edmund Jacobs, Executive Director
 Mail Stop F751
 1675 Aurora Court
 Aurora, Colorado 80045
 USA
 Phone: 720-848-3950 Ext.
 ejacobs@comesa.org

Establishment Recovery Establishment: Yes
 Parent Manufacturing Establishment FEI No.: 1000517468
 Testing For Micro-Organisms Only: No
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Pentoneal Membrane												
Sclera		X	X		X	X	X	X	X			
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Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

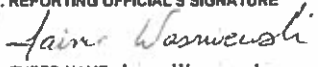
DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3011894483	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2018 Last Registration Receipt Date: 12/11/2018 Summary Report Print Date: 12/19/2018
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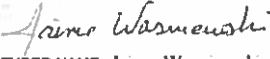
Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Monarch Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3845 Ext.:	Reporting Official: Edmond Jacobs, Executive Director Mail Stop F751 1875 Aurora Court Aurora, Colorado 80045 USA Phone: 720-848-3850 Ext. ejacobs@corneas.org	Satellite Recovery Establishment: Yes Parent Manufacturing Establishment FEI No.: 1000317466 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)).
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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			
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):

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. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA: 16-NOV-2017 DISTRICT: Denver PRINTED BY FDA: 27-JAN-2018	1							
PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION			11. HCT/PA DESCRIBED IN 21 CFR 1271.10 12. HCT/PA REGULATED AS MEDICAL DEVICES 13. HCT/PA REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)						
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										
		Establishment Functions										
		Recover	Screen	Test			Package	Process	Store	Label	Distribute	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Rocky Mountain Lions Eye Bank 1675 Aurora Court E12049 Aurora, Colorado 80045		a. Bone										
a. PHONE 720-848-3937 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		b. Cartilage										
5. ENTER CORRECTIONS TO ITEM 4		c. Cornea	X	X				X	X	X	X	X
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Rocky Mountain Lions Eye Bank Attn: Jaime Wasniewski Mail Stop F751 1675 Aurora Court Aurora, Colorado 80045		d. Dura Mater										
a. PHONE 720-848-3934 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
b. PHONE _____		f. Fascia										
8. U.S. AGENT		g. Heart Valve										
a. E-MAIL _____ 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Jaime Wasniewski b. E-MAIL jwasniewski@corneas.org c. TITLE Quality Assurance Manager d. DATE 16-NOV-2017		h. Ligament										
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		j. Pericardium										
		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		l. Sclera	X	X		X	X	X	X	X		
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
		n. Skin										
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		p. Tendon										
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		r. Vascular Graft										
		s.										
		t.										
		u.										
		v.										

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: 3011694463	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:16-NOV-2017 DISTRICT: Denver PRINTED BY FDA:27-JAN-2018																																																																																																																																																																																																																																																																																																																																																																																															
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TYPED NAME Jaime Wasniewski b. E-MAIL jwasniewski@corneas.org c. TITLE Quality Assurance Manager d. DATE 16-NOV-2017	PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr><td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>b. 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