DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE ISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	I: 1000517466		Other I Blood Device Drugs	l: es:	istrations:		Last Ann Last Reg	For Last Submissic ual Registration Ye jistration Receipt D y Report Print Date	ate: 12/07/2023
Legal Name and Location: Rocky Mountain Lions Eye Bank 1675 Aurora Court El 2049			Michelle Mail Sto 1675 Au	ng Official: Carlino, Quality / p F751, El 2049 rora Court Colorado 80045	Assurance M	lanager				Parent Man Testing For Note: FDA ac		ishment FEI No.: 1000517466
Aurora, Colorado 80045 USA Phone: 720-848-3937	Ext.:		Phone:	720-848-3937 Ex @corneas.org	t.							HCT/P is licensed or approved by FDA (21 CFR
					Establishn	nent Functio	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	x	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:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CFI	ERVICE ISTRATION D LISTING FOR HUMAN CELLS, SUE-BASED PRODUCTS		FEI	: 3011694463		Other Blood Devic Drugs	l: es:	istrations:	:	Last Ann Last Reg	For Last Submissic ual Registration Ye istration Receipt D y Report Print Date	bar: 2024 nate: 12/07/2023
Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3937	Ext.:		Michelle 1675 Au Mail Sto Aurora, 0 USA Phone:	ng Official: Carlino, Quality. rora Court p F751, El 2049 Colorado 80045 720-848-3937 Ex @corneas.org		lanager				Parent Man Testing For Note: FDA ac constitute a d	etermination that a	ishment FEI No.: 1000517466
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Establishr Package	nent Functio 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	x	X	х	x			
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	х		х	х	x	х	х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

FEI: 3011694463

Legal Name:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE ISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	: 3011694463		Other Blood Devic Drugs	l: es:	istrations:		Last Ann Last Reg	For Last Submissic ual Registration Ye istration Receipt D / Report Print Date	ate: 12/19/2022	ion/Listing
Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3937	Ext.:		John Lo 1675 Au Mail Stop Aurora, 0 USA Phone:	ng Official: ohmeier, Executive p F751, El 2049 Colorado 80045 720-848-3937 Ex r@corneas.org						Parent Mann Testing For Note: FDA ac constitute a d	etermination that a	shment FEI No.: s Only: ablishment registration : n establishment is in co	Yes 1000517466 No and HCT/P listing does not mpliance with applicable pproved by FDA (21 CFR
					Establishn	nent Functio	ons						
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Prop	rietary Name(s)
Amniotic Membrane													
Blood Vessel													
Bone													
Cardiac Tissue - non-valved													
Cartilage													
Cornea		х	х		х	х	x	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	x	х	Х				
Semen													
Skin													
Tendon													
Testicular Tissue													
Tooth Pulp													
Umbilical Cord Tissue													

Proprietary Name(s):

FEI: 3011694463

Legal Name:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE ISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	: 1000517466		Other Blood Devic Drugs	l: es:	istrations:		Last Ann Last Reg	For Last Submissic ual Registration Ye jistration Receipt D y Report Print Date	ate: 12/19/2022
Legal Name and Location: Rocky Mountain Lions Eye Bank 1675 Aurora Court El 2049			John Lo Mail Stop 1675 Au	ng Official: hmeier, Executive p F751, El 2049 rora Court Colorado 80045	e Director					Parent Man Testing For Note: FDA ac		shment FEI No.: 1000517466
Aurora, Colorado 80045 USA Phone: 720-848-3937	Ext.:		Phone:	720-848-3937 Ex r@corneas.org	t.							HCT/P is licensed or approved by FDA (21 CFR
					Establishn	nent Functio	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	х	X	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:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE IISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	: 1000517466		Other Blood Devic Drugs	: es:	istrations:		Last Ann Last Reg	For Last Submissic ual Registration Ye istration Receipt D y Report Print Date	ate: 12/06/2021	ation/Listing
Legal Name and Location: Rocky Mountain Lions Eye Bank 1675 Aurora Court E12049			Ashi Mo Mail Stop 1675 Au	ng Official: pore, Quality Assu p F751 rora Court Colorado 80045	rance Manag	jer				Parent Man Testing For Note: FDA ac		ishment FEI No.: s Only: tablishment registration	Yes 1000517466 No n and HCT/P listing does not
Aurora, Colorado 80045 USA Phone: 720-848-3937	Ext.:		Phone:	720-848-3934 Ex @corneas.org	t.								compliance with applicable approved by FDA (21 CFR
					Establishn	nent Functio	ons						
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Pro	prietary Name(s)
Amniotic Membrane													
Blood Vessel													
Bone													
Cardiac Tissue - non-valved													
Cartilage													
Cornea		x	х		х	х	x	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:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE ISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	: 3011694463		Other Blood Device Drugs	l: es:	istrations:		Last Ann Last Reg	For Last Submissio ual Registration Ye istration Receipt D y Report Print Date	ear: 2022 ate: 11/16/2021
Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3945	Ext.:		Ashi Mo 1675 Au Mail Sto Aurora, 0 USA Phone:	ng Official: nore, Quality Assu rora Court p F751 Colorado 80045 720-848-3934 Ex @corneas.org	Testing For Micro-Organisms Only: Note: FDA acceptance of an establishment registration a constitute a determination that an establishment is in con							shment FEI No.: 1000517466 s Only: No ablishment registration and HCT/P listing does not n establishment is in compliance with applicable
					Establishn	nent Functio	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	x		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: 3011694463

Legal Name:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE IISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	: 1000517466		Other I Blood Device Drugs	: es:	istrations:		Last Ann Last Reg	For Last Submissic ual Registration Ye istration Receipt D y Report Print Date	ate: 11/17/2020	ation/Listing
Legal Name and Location: Rocky Mountain Lions Eye Bank 1675 Aurora Court E12049			Luana M Mail Sto 1675 Au	ng Official: Marvin, Quality As p F751 rora Court Colorado 80045	surance Man	ager				Parent Man Testing For Note: FDA ac		ishment FEI No.: s Only: ablishment registration	Yes 1000517466 No n and HCT/P listing does not compliance with applicable
Aurora, Colorado 80045 USA Phone: 720-848-3937	Ext.:		Phone:	720-848-3934 Ex 2corneas.org	t.								approved by FDA (21 CFR
					Establishn	nent Functio	ons						
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Pro	prietary Name(s)
Amniotic Membrane													
Blood Vessel													
Bone													
Cardiac Tissue - non-valved													
Cartilage													
Cornea		x	х		х	х	x	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):

FEI: 1000517466

Legal Name:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE ISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	: 3011694463		Other I Blood Device Drugs	l: es:	istrations:		Last Ann Last Reg	For Last Submissic ual Registration Ye istration Receipt D y Report Print Date	ate: 11/17/2020	ion/Listing
Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Moncrieff Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3945	Ext.:		Luana M 1675 Au Mail Stop Aurora, 0 USA Phone:	ng Official: Marvin, Quality As rora Court ⊳ F751 Colorado 80045 720-848-3934 Ex ⊉corneas.org		ager				Parent Mann Testing For Note: FDA ac constitute a d	etermination that a	shment FEI No.: s Only: ablishment registration : n establishment is in co	Yes 1000517466 No and HCT/P listing does not mpliance with applicable pproved by FDA (21 CFR
					Establishn	nent Functio	ons						
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Prop	rietary Name(s)
Amniotic Membrane													
Blood Vessel													
Bone													
Cardiac Tissue - non-valved													
Cartilage													
Cornea		x	х		х	х	x	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):

FEI: 3011694463

Legal Name:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CF	ERVICE IISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	I: 1000517466		Other Blood Devic Drugs	l: es:	istrations:	-	Last Ann Last Reg	For Last Submissic ual Registration Ye istration Receipt D / Report Print Date	ate: 11/20/2019	tion/Listing
Legal Name and Location: Rocky Mountain Lions Eye Bank 1675 Aurora Court E12049			Luana Mail Sto 1675 Au	ng Official: Marvin, Quality As p F751 rora Court Colorado 80045	surance Man	ager				Parent Man Testing For Note: FDA ac		shment FEI No.: s Only: ablishment registratior	Yes 1000517466 No and HCT/P listing does not ompliance with applicable
Aurora, Colorado 80045 USA Phone: 720-848-3937	Ext.:		Phone:	720-848-3934 Ex ⊉corneas.org	t.								approved by FDA (21 CFR
					Establishn	nent Functio	ons						
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proj	prietary Name(s)
Amniotic Membrane													
Blood Vessel													
Bone													
Cardiac Tissue - non-valved													
Cartilage													
Cornea		x	х		х	х	x	х	x				
Dura Mater													
Embryo													
Fascia													
Heart Valve													
HPC Apheresis													
HPC Cord Blood													
Ligament													
Nerve Tissue													
Oocyte													
Ovarian Tissue													
Pancreatic Islet Cells - autologous													
Parathyroid													
Pericardium													
Peripheral Blood Mononuclear Cells													
Peritoneal Membrane													
Sclera		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):

FEI: 1000517466

Legal Name:

DEPARTMENT OF HEALTH AN PUBLIC HEALTH S FOOD AND DRUG ADMIN ESTABLISHMENT REGISTRATION AN TISSUES, AND CELLULAR AND TIS DESCRIBED IN 21 CFI	ERVICE ISTRATION D LISTING FOR HUMAN CELLS, SSUE-BASED PRODUCTS		FEI	: 3011694463		Other Blood Devic Drugs	l: es:	istrations:	:	Last Ann Last Reg	For Last Submissio ual Registration Ye istration Receipt D y Report Print Date	ear: 2020 rate: 11/20/2019
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. Imarvin@corneas.org Establishment Functions								etermination that a	ishment FEI No.: 1000517466
					Establishr	nent Functio	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				
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				
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3011694463

Legal Name:

DEPARTMENT OF HEALTH AND HUMAN SFRVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUICTS DESCRIBED W 21 CFR 1271.10	FE): 1000517468	Other FDA Registrations: Blaod: Devices: Druge:	Resson For Last Submission. Annual Registra Lest Annual Registration Year: 2019 Last Registration Receipt Date: 12/11/2016 Summary Report Print Date: 12/10/2016	ionRisting
Legal Name and Location: Rocky Mountain Liona Eye Bank 1875 Aurora Count E 12049	Reporting Official: Edmund Jacobs, Executive Direc Mail Stop F751 1675 Aurora Court	lar	Solelitic Recovery Establishment: Parent Manufacturing Establishment FEI No.: Teating For Micro-Organisme Only:	Yes 1000517455 No
Aurore, Colorada 80045 USA Phone 720-848-3937 Ertl.;	Aurora, Colonado 80045 USA Phone: 720-848-3950 Ext. ejacobs@comesa.org		Note FDA acceptance of an establishment registration constitute a determination that an establishment is in ca rules and regulations or that the HCT/P is Scansed or a 1271_27(b)).	impliance with applicable

		-			Establishr	rant Functio	ens.		12.12			
HCTIP(=)	Danor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Dele of Discontinuance	Date of Hesumption	₹roprietary Name(s)
Anniobe Membrane	1.74	nation State Non Junior	Ave. 6. Int. Proc.									
Blood Vessat							-					a land a set of the second
Boris		a land	-		1							
Candian Tissue - non-velved		_						1				
Carblage		_	L		1							
Comea		x	x		ж	×	х	×	x			
Dura Mater											1 2 2 22	
Embryo		_					1					
Fascia		21-25-1	1									
Heart Valve												
HPC Apharasis			1		<u>i</u>							
HPC Cord Blood										1		
Ugament			1									
Herve T. szup												
Oocyle				1			_					
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parethyroid		1									in the second second	
Pericardium		1	1					111-125	-	·		
Peripheral Blood Mononuclear Cells		1	1		lane and							
Pentoneal Membrane		-					1					
Sciern		x	x		x	х	x	x	x	1		
Semen							-					
Skin		1		1								
Tendon	1 1 10 18 19 19	- torner						Same				
Testcular Tissue											inclusion of pair with	
Tooth Pulp												
Umbilical Cont Tissue		-										

FEL = 1000517466

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FDA information collection CMB Control number: 0918-0543, expiration date: 6/30/2020 Legal Name

Additional Information: No addapnal information provided.

Proprietary Nerre(s):

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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND ORUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3011894463	Other FDA Registrations: Blaod: Devicus: Drugs:	Reason For Last Submission Annual Registra Last Annual Registration Yesir 2019 Last Registration Receipt Date 12/11/2018 Summary Report Print Date: 12/15/2018	Last Annual Registration Year 2019 Last Registration Receipt Date 12/11/2018						
Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Monomit Place Suite C	Reporting Official: Edmand Jacobs, Executive Director Mail Slop F751 1875 Aurora Court Aurora, Colorada 50945		SaleXite Recovery Establishment: Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only:	Yes 1000317466 Na						
Aurona Colorado 80010 USA Phone 720-848-3945 Est.:	USA Phone 720-848-3850 Est, ejacobs@comeas.org		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)).							

	}			Establishr	nent Functi	ei15					
Doner Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Data of Discontinuance	Data of Resumption	Proprietary Name(s)
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		Doner Typeis) Recover	Doner Typejs) Racover Screen	Donor Type(s) Recover Screen Donor Testing		Donor Type(s) Racover Screen Donor Testing Package Process		Donor Type(s) Racover Screen Donor Testing Package Process Store Label Image: Screen Image:	Donor Type(+) Screen Donor Testing Package Procests Store Label Distribute Image: Screen Ima	Donor Type(s) Racover Screen Donor Testing Package Process Stare Label Database Image: Stare <	Bonor Typei(s) Racover Screen Bonor Tessing Package Process Stare Label Data of Data of Image: Stare S

FEI: 3011694403

FDA Internation collection DMB Control number: 0910-0543; expiration data: 6/30/2020 Legal Name

Additional Information: No additional information provided.

Proprietary Name(#):

10.00

FDA Information collection CI48 Control number: 0910-0543, expiration date: 6/30/2020 Legal Name:

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE	1. REGISTRATION NUMBER (FDA Establishment Identifier)			a.[AL REGIS	STRATIC	N/LISTIN							
FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELL	S. TISSUES.	SUES, FEI: 1000517466				b	a seat	INUAL REGISTRATION / LISTING						7-JAN-2018	
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/P	Ps)			G	CHAI	IGE IN IN	FORMA	TION							
(See reverse side for instructions)	-,					d.	INAC	TIVE			_				
PART I - ESTABLISHMENT INFORMATION	PART II - PE			- 626			11. HCT/PA DESCRIBED CFR 1271.10		몽몽문수						
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT						T/Ps						13. NCT/Ps REGULATED DRUGS OR BIOLOGICAL		
a. BLOOD FDA 2830 NO.		Estat					ablishment Functions						<u>E</u> SUS	14. PROPRIETARY NAME(S)	
	Types of	HCT/Ps	Recover	Screen	Test		Process	Store	Label	Distribute	2	12. HCT/Ps REGULATED AS MEDICAL DEVICES	2	•••	
b. DEVICES FDA 2891 NO.			Kecover	SCIMIN	Tesc	6.acceda	PTOCESS	2070	Later	UNUIDUR	- -	G.	AS 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														
1675 Aurora Court E 12049	c. Comea		x	x		x	x	x	x	X	x			1	
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											(T			
5. ENTER CORRECTIONS TO ITEM 4	h, Ugament		b 1									-		1	
	n. eguntetti	(7)	-	-	1.1.1		-	-	-						
 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													
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	j. Pericardium											-	1		
Mail Stop F751	k. Peripherat	Autologous													
1675 Aurora Court	Blood Stem	Family Related						1				1			
Aurota, Colorado 80045	I. Sciera		x	x		x	x	x	X	x	x				
C		SIP	1			1			-				· · · · · ·		
a PHONE 720-848-3934 EXT 7. ENTER CORRECTIONS TO ITEM 6 EXT	m. Semen	Directed Anonymous	-		_			_							
b. PHONE	n. Skin														
	o. Somatic Cell Therapy Products	Autologous Family Related													
8. U.S. AGENT	p. Tendon														
	g. Umbilical	Autologous	-	-		-		1					-		
	Cord Blood	Family Related Allogeneic								_					
a. E-MAIL	r, Vascular Graft														
P. REPORTING OFFICIAL'S SIGNATURE	8.														
faine Wasniewsh	t						-					-			
a. TYPED NAME Jaime Wasniewski	u,		1			1	-		-			1			
b. E-MAIL jwasniewski@corneas.org												_	15		
c. TITLE Quality Assurance Manager d. DATE 16-NOV-2017	۷.		1			1									

FORM FDA - 3356 (7/17)

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

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DEP	1. REGISTRATION NUMBER (FDA Establishment Identifier)					a. [INITI		TRATIO	NILISTING					
ESTABLISHMENT R	S. TISSUES.	SSUES, FEI: 3011694463			b. X ANNUAL REGISTRATION / LISTIN						PRINTED BY FOA:27-JAN-2018				
AND CEL	Ps)			c. CHANGE IN INFORMATION											
PART I - ESTABLISHMENT	PART II - PR	ODUCT INFO	RMATIC	DN							요문≒	in Ra	<u>명</u> 모류:		
3. OTHER FDA REGISTRATION	10. ESTABLISH	MENT FUNCTIO	NS AND	TYPES	OF HC	T/Ps				-	11. HCT/Pa DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS		
a. BLOOD FDA 2830	NO.		Establishment Functions									283	223 223	문흥숙화	14. PROPRIETARY NAME(S)
a. 02000 FDA 2030		Types of	NCT (Be									°₽́	₩ S>	F 6	to some for t
b, DEVICES FDA 2691	NO	(ypes of	nutra	Recover	Screen	Test	Package	Process	Store	Label	Distribute	브		20 01	
c. DRUG FDA 2656	NO.													ě.	
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post office code)	e legal name, number and street, city, state, country, and	a. Bone		<u> </u>	ļ		ļ		ļ	-					
Rocky Mountain Lions Ey	e Bank	b. Cartilage				[
15201 East Moncrieff Plac Aurora, Colorado 80010	e Suite C	c. Comea						x		x		X			
		d. Dura Mater													
a. PHONE 720-848-3945	EXT	e. Embryo	StP Directed Anonymous												
a. PHONE 220-545-3943 b. X. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 1000517466 C. TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4		t. Fascia													
		g. Hearl Valve													
		h. Ligament													
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable,	I. Oocyte	SIP Directed													
number and street, city, state, country, and post office code) Rocky Mountain Lions Eye Bank		j. Pericardium						-							
Attn: Jaime Wasniewski Mail Stop F751 1675 Aurora Court		k, Peripheral Blood Stem	Autologous Family Related												
Aurora, Colorado 80045		1. Sclera						x		x		x			
a. PHONE 7208483934	EXT	m. Semen	SIP Directed												
7, ENTER CORRECTIONS TO ITE			Anonymous												
		n. Skin													
		o. Somatic Cell Therapy Products	Autologous Family Related			-									
B. U.S. AGENT		p. Tendon													
		q. Umbilicat Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL		r. Vascular Graft													
. REPORTING OFFICIAL'S SIGN		5.				Ì									
frimer Wasmen		t													
a. TYPED NAME Jaime Wasni b. E-MAIL jwasniewski@corr		u.													
c. TITLE Quality Assurance N	-	v.	·												
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