

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)).

Establishment Functions

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	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 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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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 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
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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: 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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Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X	X	X	X	X			
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Fascia												
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HPC Cord Blood												
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Nerve Tissue												
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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)).

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):

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Legal Name:

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 PUBLIC HEALTH SERVICE
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 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

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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

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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**

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												
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Parathyroid												
Pericardium												
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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
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

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)
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Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X	X	X	X	X			
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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):

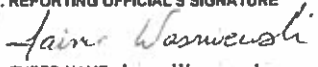
DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10	FEI: 3011894483	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last 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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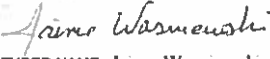
Legal Name and Location: Rocky Mountain Lions Eye Bank 15201 East Monarch Place Suite C Aurora, Colorado 80010 USA Phone: 720-848-3845	Reporting Official: Edmond Jacobs, Executive Director Mail Stop F751 1875 Aurora Court Aurora, Colorado 80045 USA Phone: 720-848-3850 Ext. ejacobs@corneas.org	Satellite Recovery Establishment: Yes Parent Manufacturing Establishment FEI No.: 1000517466 Testing For Micro-Organisms Only: No <i>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)).</i>
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
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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																																																																																																																																																																																																																																																	
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. 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		<table border="1" style="width:100%; border-collapse: collapse; font-size: x-small;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="9">Establishment Functions</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> <th></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></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. Embryo</td><td colspan="2"><input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>f. Fascia</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>g. Heart Valve</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>h. Ligament</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>i. Oocyte</td><td colspan="2"><input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>j. Pericardium</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>k. Peripheral Blood Stem</td><td colspan="2"><input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>l. Sclera</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr> <tr><td>m. Semen</td><td colspan="2"><input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>n. Skin</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>o. Somatic Cell Therapy Products</td><td colspan="2"><input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>p. Tendon</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood</td><td colspan="2"><input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>r. Vascular Graft</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>s.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>t.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>u.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>v.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table>			Types of HCT / Ps	Establishment Functions									Recover	Screen	Test	Package	Process	Store	Label	Distribute		a. Bone										b. Cartilage										c. Cornea	X	X		X	X	X	X	X	X	d. Dura Mater										e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous									f. Fascia										g. Heart Valve										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	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.									
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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 (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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