## 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: 3000718537

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/18/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

Sioux Falls, South Dakota 57107

Phone: 605-373-1008

3000718537

FEI:

USA

South Dakota Lions Eye and Tissue Bank, Inc.(dba Dakota Lions Sight & Health)

4501 W 61st St North

Ext.:

Reporting Official:

Matthew E Arnett. Chief Administrative Officer

4501 W 61st St North

Sioux Falls, South Dakota 57107

Phone: 605-373-1008 Ext. marnett@dakotasight.org

Satellite Recovery Establishment:

No

Parent Manufacturing Establishment FEI No.:

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 Date of Date of Proprietary Name(s) Donor Type(s) HCT/P(s) Screen Donor Testina Package Process Store Label Distribute Discontinuance Resumption Х Amniotic Membrane Χ Blood Vessel Х Χ Χ Χ Bone Cardiac Tissue - non-valved Х Χ Cartilage Χ Χ Х Х Х Х Х Χ Х Cornea Dura Mater Embryo Fascia Χ Χ Heart Valve Х Χ **HPC Apheresis** HPC Cord Blood Χ Ligament Х Nerve Tissue Х Х Oocyte Ovarian Tissue Pancreatic Islet Cells - autologous Parathyroid Pericardium Х Χ Peripheral Blood Mononuclear Cells Peritoneal Membrane Χ Χ Х Χ Χ Sclera Χ Χ Semen Skin Х Χ Tendon Х Х Testicular Tissue Tooth Pulp Χ Χ **Umbilical Cord Tissue** 

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

Proprietary Name(s):

FEI: 3000718537

Legal Name: South Dakota Lions Eye and Tissue Bank, Inc.(dba Dakota Lions Sight & Health)

## 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: 3006850594

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/18/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

South Dakota Lions Eye and Tissue Bank, Inc. (dba Dakota Lions Sight & Health)

1774 E Centre Street

Suite 4

Rapid City, South Dakota 57703

USA

Ext.: Phone: 605-373-1008

Reporting Official:

Matthew E Arnett. Chief Administrative Officer

4501 W 61st St North

Sioux Falls, South Dakota 57107

Phone: 605-373-1008 Ext. marnett@dakotasight.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 3000718537

Testing For Micro-Organisms Only:

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

		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		Х										
Blood Vessel		Х										
Bone		Х										
Cardiac Tissue - non-valved		Х										
Cartilage		Х										
Cornea		X					Х					
Dura Mater												
Embryo												
Fascia		Х										
Heart Valve		Х										
HPC Apheresis												
HPC Cord Blood												
Ligament		Х										
Nerve Tissue		Х										
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		Х										
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х					Х					
Semen												
Skin		Х										
Tendon		Х										
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue		X										

FEI:

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

Proprietary Name(s):

FEI: 3006850594

Legal Name: South Dakota Lions Eye and Tissue Bank, Inc. (dba Dakota Lions Sight & Health)

## 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: 3011394216

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/18/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

South Dakota Lions Eye and Tissue Bank, Inc. (dba Dakota Lions Sight & Health)

1003 E Interstate Ave Suite 3

Bismarck, North Dakota 58503

USA

Ext.: Phone: 605-373-1008

Reporting Official:

Matthew E Arnett. Chief Administrative Officer

4501 West 61st Street North

Sioux Falls, South Dakota 57107

Phone: 605-373-1008 Ext. marnett@dakotasight.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 3000718537

Testing For Micro-Organisms Only:

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

					Establishr	nent Function	ons					
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane		Х										
Blood Vessel		X										
Bone		Х										
Cardiac Tissue - non-valved		Х										
Cartilage		Х										
Cornea		Х					Х					
Dura Mater												
Embryo												
Fascia		Х										
Heart Valve		Х										
HPC Apheresis												
HPC Cord Blood												
Ligament		Х										
Nerve Tissue		х										
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		х										
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		х					Х					
Semen												
Skin		Х										
Tendon		Х										
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue		Х										

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3011394216

Legal Name: South Dakota Lions Eye and Tissue Bank, Inc. (dba Dakota Lions Sight & Health)

# 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: 3012792221

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/18/2024 Summary Report Print Date: 12/05/2024

Legal Name and Location:

South Dakota Lions Eye & Tissue Bank, Inc. (dba Dakota Lions Sight & Health)

Ext.:

1321 23rd Street S

Suite 1A

Fargo, North Dakota 58103

USA

Phone: 605-373-1008

Reporting Official:

Matthew E Arnett. Chief Administrative Officer

4501 W 61st St N

Sioux Falls, South Dakota 57107

Phone: 605-373-1008 Ext. marnett@dakotasight.org

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.: 3000718537

Testing For Micro-Organisms Only:

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

Yes

					Establishn	nent Functio	ons			Date of Date of Resumption		
HCT/P(s) Donor Type(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute		Date of Resumption	Proprietary Name(s)
Amniotic Membrane		Х										
Blood Vessel		х										
Bone		X										
Cardiac Tissue - non-valved		X										
Cartilage		Х										
Cornea		Х					Х					
Dura Mater												
Embryo												
Fascia		Х										
Heart Valve		X										
HPC Apheresis												
HPC Cord Blood												
Ligament		Х										
Nerve Tissue		Х										
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		X										
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х					Х					
Semen												
Skin		X										
Tendon		Х										
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue		Х										

FEI:

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3012792221 Legal Name: South Dakota Lions Eye & Tissue Bank, Inc. (dba Dakota Lions Sight &