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: 3011394216

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:

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 Quality Officer

4501 West 61st Street North

Sioux Falls, South Dakota 57107

Phone: 605-373-1008 Ext. 6067

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								· I		
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		Х										
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												

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

FEI: 3011394216

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