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: 3000718537

Reporting Official:

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)

4501 W 61st St North

Matthew E Arnett, Chief Quality 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)).

Sioux Falls, South Dakota 57107

USA

Phone: 605-373-1008

Ext.:

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

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3000718537

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