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: 3012792221

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

Ext.:

1321 23rd Street S

Suite 1A

Fargo, North Dakota 58103

USA

Phone: 800-245-7846

Reporting Official:

Matthew E Arnett, Chief Quality Officer

4501 W 61st St N

Sioux Falls, South Dakota 57107

USA

Phone: 605-373-1008 Ext. 6067

marnett@dakotasight.org

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 3000718537

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)).

	Donor Type(s)	Establishment Functions										
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		X										
Bone		X										
Cardiac Tissue - non-valved		X										
Cartilage		X										
Cornea		х					Х					
Dura Mater												
Embryo												
Fascia		х										
Heart Valve		х										
HPC Apheresis												
HPC Cord Blood												
Ligament		х										
Nerve Tissue												
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												

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Additional Information:	No additional information provided

Proprietary Name(s):

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