

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: Change in Information Last Annual Registration Year: 2019 Last Registration Receipt Date: 12/10/2018 Summary Report Print Date: 12/19/2018
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Legal Name and Location: South Dakota Lions Eye & Tissue Bank, Inc. (dba Dakota Lions Sight & Health) 100 S Fourth St Suite LL18 Fargo, North Dakota 58103 USA Phone: 701-478-9222 Ext.:	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)).
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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		X										
Bone		X										
Cardiac Tissue - non-valved		X										
Cartilage		X										
Cornea		X					X					
Dura Mater												
Embryo												
Fascia		X										
Heart Valve		X										
HPC Apheresis												
HPC Cord Blood												
Ligament		X										
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		X										
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		X					X					
Semen												
Skin		X										
Tendon		X										
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):