See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 6/30/2020

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 (HCT/Ps)

(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)
FEI: 3011394216

2. REASON FOR SUBMISSION
a. [ ] INITIAL REGISTRATION / LISTING
b. [X] ANNUAL REGISTRATION / LISTING
c. [ ] CHANGE IN INFORMATION
d. [ ] INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:16-NOV-2017
DISTRICT: Minneapolis
PRINTED BY FDA:27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
South Dakota Lions Eye and Tissue Bank, Inc. (dba Dakota Lions Sight & Health)
200 East Main Ave
Suite 102A
Bismarck, North Dakota 58501

a. PHONE 701-250-9390 EXT
b. [X] SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3000718537
c. [ ] TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
South Dakota Lions Eye and Tissue Bank, Inc. (dba Dakota Lions Sight & Health)
Attn: Matthew E. Arnett
4501 West 61st Street North
Sioux Falls, South Dakota 57107

a. PHONE 605-373-1008 EXT 6067

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Matthew E. Arnett
b. E-MAIL marnett@dakotasight.org
c. TITLE Chief Quality Officer d. DATE 16-NOV-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone	X								X			
b. Cartilage	X								X			
c. Cornea	X					X			X			
d. Dura Mater												
e. Embryo [ ] SIP [ ] Directed [ ] Anonymous												
f. Fascia	X								X			
g. Heart Valve	X								X			
h. Ligament	X								X			
i. Oocyte [ ] SIP [ ] Directed [ ] Anonymous												
j. Pericardium	X								X			
k. Peripheral Blood Stem [ ] Autologous [ ] Family Related [ ] Allogeneic												
l. Sclera	X					X			X			
m. Semen [ ] SIP [ ] Directed [ ] Anonymous												
n. Skin	X								X			
o. Somatic Cell Therapy Products [ ] Autologous [ ] Family Related [ ] Allogeneic												
p. Tendon	X								X			
q. Umbilical Cord Blood [ ] Autologous [ ] Family Related [ ] Allogeneic												
r. Vascular Graft	X								X			
s.												
t.												
u.												
v.												