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)

1. REGISTRATION NUMBE (FDA Establishment Identifier)						
FEI: 3012792221						

2. REASON FOR SUBMISSION									
a. 🗌	INITIAL REGISTRATION	ON / LISTING							
b	ANNUAL REGISTRAT	ION / LISTING							
c. X	CHANGE IN INFORMA	ATION							

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:12-APR-2018 DISTRICT: Minneapolis PRINTED BY FDA:12-APR-2018

(See reverse side for instructions)	,					d.	INAC	TIVE						
PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION					유명.1	돌유12	B R R 13.						
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps						R CR	SET	Z S S S S S S S S S S S S S S S S S S S					
a. BLOOD FDA 2830 NO.	Establishment Functions					,	71.16 71.16	E A Ps	SICA ATE	14. PROPRIETARY NAME(S)				
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		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	NAME(0)
c. DRUG FDA 2656 NO													Ø	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone		X								X			
South Dakota Lions Eye & Tissue Bank, Inc. (dba Dakota Lions Sight & Health)	b. Cartilage		X								X			
100 S Fourth St Suite LL18	c. Cornea		X					X			X			
Fargo, North Dakota 58103	d. Dura Mater													
a. PHONE 701-478-9222 EXT	e. Embryo	SIP Directed Anonymous												
b. X SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3000718537	f. Fascia		X								X			
c. L_\ TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X								X			
	h. Ligament		X								X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)	i. Oocyte	☐ SIP ☐ Directed ☐ Anonymous												
Dakota Lions Sight & Health Attn: Matthew E. Arnett	j. Pericardium		X								X			
4501 W 61st St N Sioux Falls, South Dakota 57107	k. Peripheral Blood Stem	☐ Autologous ☐ Family Related ☐ Allogeneic												
	I. Sclera		X					X			X			
a. PHONE 605-373-1008 EXT 6067 7. ENTER CORRECTIONS TO ITEM 6	m. Semen	SIP Directed Anonymous												
b. PHONE	n. Skin		X								X			
	o. Somatic Cell Therapy Products	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon		X								X			
	q. Umbilical Cord Blood	Autologous Family Related Allogeneic												
a. E-MAIL	r. Vascular Graft		X								X			
9. REPORTING OFFICIAL'S SIGNATURE	S.													
a. TYPED NAME Matthew E. Arnett	t.													
b. E-MAIL marnett@dakotasight.org	u.													
c. TITLE Chief Quality Officer d. DATE 16-NOV-2017	V.													

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

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1.	REC	SISTRATION NUM	IBER
	/EDA	Establishment Identi	fior\

FEI: 3012792221

ADDITIONAL INFORMATION:

South Dakota Lions Eye & Tissue Bank, Inc. (dba Dakota Lions Sight & Health) FEI number changed from 3012796872 to the correct FEI 3012792221.

Tissue Registration Coordinator

Proprietary Name(s):

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