

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3000718537	<b>2. REASON FOR SUBMISSION</b> a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:16-NOV-2017 DISTRICT: Minneapolis PRINTED BY FDA:27-JAN-2018
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									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)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Establishment Functions												
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
<b>4. PHYSICAL LOCATION</b> (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) 4501 W 61st St North Sioux Falls, South Dakota 57107  a. PHONE 605-373-1008 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X							X			
	b. Cartilage	X	X							X			
	c. Cornea	X	X		X	X	X	X	X	X			
	d. Dura Mater												
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	f. Fascia	X	X							X			
	g. Heart Valve	X	X							X			
	h. Ligament	X	X							X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium	X	X							X			
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	l. Sclera	X	X		X	X	X	X	X	X			
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	n. Skin	X	X							X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Dakota Lions Sight & Health Attn: Matthew E. Arnett 4501 W 61st St North Sioux Falls, South Dakota 57107  a. PHONE 605-373-1008 EXT _____	p. Tendon	X	X							X			
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft	X	X							X			
<b>7. ENTER CORRECTIONS TO ITEM 6</b> a. PHONE _____ b. PHONE _____	s. Nerve Tissue	X	X							X			
	t.												
	u.												
	v.												
<b>8. U.S. AGENT</b>  a. E-MAIL _____													
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Matthew E. Arnett b. E-MAIL marnett@dakotasight.org c. TITLE Chief Quality Officer d. DATE 16-NOV-2017													