

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: 3011394216	<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													
	Types of HCT / Ps	Establishment Functions												
		Recover	Screen	Test	Package	Process	Store	Label	Distribute					
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. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT 3000718537 c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X								X				
	b. Cartilage	X								X				
	c. Cornea	X					X			X				
	d. Dura Mater													
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
	f. Fascia	X								X				
	g. Heart Valve	X								X				
	h. Ligament	X								X				
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
	j. Pericardium	X								X				
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 _____	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
	l. Sclera	X					X			X				
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
	n. Skin	X								X				
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
	p. Tendon	X								X				
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
	r. Vascular Graft	X								X				
	8. U.S. AGENT  a. E-MAIL _____	s.												
		t.												
u.														
v.														
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														

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	b. Cartilage	X								X				
	c. Cornea	X					X			X				
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a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone	X									X		
	b. Cartilage	X									X		
	c. Cornea	X					X				X		
	d. Dura Mater												
	e. Embryo												
	f. Fascia	X									X		
	g. Heart Valve	X									X		
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	i. Oocyte												
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Cornea</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>d. Dura Mater</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>f. Fascia</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>g. Heart Valve</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>h. Ligament</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>j. Pericardium</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>l. Sclera</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>n. Skin</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>p. Tendon</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>r. Vascular Graft</td> <td style="text-align: center;">X</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>s. 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