




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: 3000718334

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

VALIDATED BY FDA USE ONLY
VALIDATED BY FDA: 20-NOV-2017
DISTRICT: Minneapolis
PRINTED BY FDA: 27-JAN-2018

PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION										14. PROPRIETARY NAME(S)						
3. OTHER FDA REGISTRATIONS		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS																
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)		Establishment Functions																
5. ENTER CORRECTIONS TO ITEM 4		Types of HCT / PS										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				
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)		Recover	Screen	Test	Package	Process	Store	Label	Distribute									
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone																
Lions Eye Bank of Wisconsin, Inc. 2401 American Lane Madison, Wisconsin 53704-3101		b. Cartilage																
a. PHONE 608-233-2354 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		c. Cornea	X			X	X	X	X	X								
5. ENTER CORRECTIONS TO ITEM 4		d. Dura Mater																
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Lions Eye Bank of Wisconsin Attn: Jack Ford 2401 American Lane Madison, Wisconsin 53704-3101		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
a. PHONE 608-233-2354 EXT 204 b. PHONE _____		f. Fascia																
7. ENTER CORRECTIONS TO ITEM 6		g. Heart Valve																
8. U.S. AGENT		h. Ligament																
a. E-MAIL _____ b. TYPED NAME Jack Ford c. TITLE Quality Systems Director		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
9. REPORTING OFFICIAL'S SIGNATURE 		j. Pericardium																
d. DATE 20-NOV-2017		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
7. ENTER CORRECTIONS TO ITEM 6		l. Sclera	X	X		X	X	X	X	X								
8. U.S. AGENT		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
a. E-MAIL _____ b. TYPED NAME Jack Ford c. TITLE Quality Systems Director		n. Skin																
9. REPORTING OFFICIAL'S SIGNATURE 		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
d. DATE 20-NOV-2017		p. Tendon																
7. ENTER CORRECTIONS TO ITEM 6		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
8. U.S. AGENT		r. Vascular Graft																
a. E-MAIL _____ b. TYPED NAME Jack Ford c. TITLE Quality Systems Director		s.																
9. REPORTING OFFICIAL'S SIGNATURE 		t.																
d. DATE 20-NOV-2017		u.																
7. ENTER CORRECTIONS TO ITEM 6		v.																