

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: 3000215040	2. REASON FOR SUBMISSION 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	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:16-NOV-2017 DISTRICT: New Orleans PRINTED BY FDA:20-DEC-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION												
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lions Eye Institute for Transplant and Research 721 Boulevard Street Shreveport, Louisiana 71104 a. PHONE 813-289-1200 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3000206983) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	Establishment Functions												
5. ENTER CORRECTIONS TO ITEM 4	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	14. PROPRIETARY NAME(S)
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Lions Eye Institute for Transplant and Research Attn: Mikelanne Schipper, CEBT 1410 N. 21st Street Tampa, Florida 33605 a. PHONE 8132891200 EXT _____	a. Bone												
7. ENTER CORRECTIONS TO ITEM 6	b. Cartilage												
8. U.S. AGENT a. E-MAIL _____	c. Cornea	X			X		X	X	X	X			
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Mikelanne Schipper, CEBT b. E-MAIL mschipper@lionseyeinstitute.org c. TITLE Director of Quality & Regulatory Affairs d. DATE 16-NOV-2017	d. Dura Mater												
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	e. Embryo												
f. Fascia	f. Fascia												
g. Heart Valve	g. Heart Valve												
h. Ligament	h. Ligament												
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	i. Oocyte												
j. Pericardium	j. Pericardium												
k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	k. Peripheral Blood Stem												
l. Sclera	l. Sclera	X			X		X	X	X	X			
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous	m. Semen												
n. Skin	n. Skin												
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	o. Somatic Cell Therapy Products												
p. Tendon	p. Tendon												
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	q. Umbilical Cord Blood												
r. Vascular Graft	r. Vascular Graft												
s.	s.												
t.	t.												
u.	u.												
v.	v.												

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PUBLIC HEALTH SERVICE
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ADDITIONAL INFORMATION:

- Lions Eye Institute for Transplant and Research inquired International Sight Restoration, Inc. in February, 2017.

LEITR acquired ISR. Shreveport was made a branch office; now utilized only for recovery. We are registering them for long-term tissue storage; long-term preserved corneas and sclera. Intermediate-term tissue will not be stored in this office.

Proprietary Name(s):