


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: 3000719872	<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: Florida PRINTED BY FDA:20-DEC-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION												
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>												
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Lions Eye Institute for Transplant & Research, Inc.  2201A East Michigan Street Orlando, Florida 32806  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	<b>Establishment Functions</b>												
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 OF 171.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Lions Eye Institute for Transplant & Research Attn: Mikelanne Schipper, CEBT 1410 North 21st Street Tampa, Florida 33605  a. PHONE 813-289-1200 EXT _____	a. Bone												
<b>7. ENTER CORRECTIONS TO ITEM 6</b> a. PHONE _____ b. PHONE _____	b. Cartilage												
<b>8. U.S. AGENT</b>  a. E-MAIL _____	c. Cornea	X			X		X	X		X			
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  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												
	f. Fascia												
	g. Heart Valve												
	h. Ligament												
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium												
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	l. Sclera	X			X		X	X		X			
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	n. Skin												
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	p. Tendon												
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft												
	s.												
	t.												
	u.												
	v.												