

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: 3001236481	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:20-NOV-2017 DISTRICT: Baltimore 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
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone																	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lions Medical Eye Bank & Research Center of Eastern Virginia, Inc. 600 Gresham Dr. Norfolk, Virginia 23507 a. PHONE 757-388-2020 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	b. Cartilage																		
	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																		
	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	X	X	X										
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																			
5. ENTER CORRECTIONS TO ITEM 4	n. Skin																		
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Lions Medical Eye Bank & Research Center of Eastern Virginia, Inc. Attn: David E. Korroch, CEBT 600 Gresham Dr. Norfolk, Virginia 23507 a. PHONE 757.388.2020 EXT _____ b. PHONE _____	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																		
	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																		
	r. Vascular Graft																		
8. U.S. AGENT a. E-MAIL _____	s.																		
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David E. Korroch, CEBT b. E-MAIL drroch@lionseyebank.org c. TITLE Executive Director d. DATE 20-NOV-2017	t.																		
	u.																		
	v.																		