


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: 3000215034	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: 13-DEC-2016 DISTRICT: New Orleans PRINTED BY FDA: 28-DEC-2016											
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 BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)					
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) Southern Eye Bank 2701 Kingman Street Suite 200 Metairie, Louisiana 70006 a. PHONE 504-891-3937 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Establishment Functions													
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store			Label	Distribute			
5. ENTER CORRECTIONS TO ITEM 4		a. Bone													
		b. Cartilage													
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Southern Eye Bank Attn: Wesley S. Thompson, CEBT 2701 Kingman Street Suite 200 Metairie, Louisiana 70006 a. PHONE 504-891-3937 EXT 1004		c. Cornea	X	X		X	X	X	X	X	X				
		d. Dura Mater													
7. ENTER CORRECTIONS TO ITEM 6		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		f. Fascia													
8. U.S. AGENT		g. Heart Valve													
		h. Ligament													
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Wesley S. Thompson, CEBT b. E-MAIL wthompson@southerneye.net c. TITLE Quality Assurance Director d. DATE 12-DEC-2016		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		j. Pericardium													
11. HCT/Ps DESCRIBED IN 21 CFR 1271.10		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				
12. HCT/Ps REGULATED AS MEDICAL DEVICES		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
		n. Skin													
13. HCT/Ps REGULATED AS BIOLOGICAL DRUGS		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
		p. Tendon													
14. PROPRIETARY NAME(S)		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
		r. Vascular Graft													
		s.													
		t.													
		u.													
		v.													