


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: 3002689373	<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: 19-NOV-2015 DISTRICT: New Orleans PRINTED BY FDA: 03-DEC-2015										
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>								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)	
<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) East Tennessee Lions Eye Bank  1924 Alcoa Hwy. , Ste U-26 Knoxville, Tennessee 37920  a. PHONE 865-305-9625 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<b>Types of HCT / Ps</b>		<b>Establishment Functions</b>										
				Recover	Screen	Test	Package	Process	Store	Label	Distribute			
<b>5. ENTER CORRECTIONS TO ITEM 4</b>		a. Bone												
		b. Cartilage												
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL.</b> (Include institution name if applicable, number and street, city, state, country, and post office code) East Tennessee Lions Eye Bank Attn: Yvette Venters 1924 Alcoa Hwy. , Ste U-26 Knoxville, Tennessee 37920  a. PHONE 865-305-9625 EXT _____		c. Cornea	X	X		X	X	X	X	X	X			
		d. Dura Mater												
<b>7. ENTER CORRECTIONS TO ITEM 6</b>		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		f. Fascia												
<b>8. U.S. AGENT</b>		g. Heart Valve												
		h. Ligament												
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Yvette Venters b. E-MAIL yventers@utmck.edu c. TITLE QA Director d. DATE 18-NOV-2015		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		j. Pericardium												
<b>11. HCT/PS DESCRIBED IN 21 CFR 1271.10</b>		k. Periphera Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		l. Sclera		X				X	X	X	X			
<b>12. HCT/PS REGULATED AS MEDICAL DEVICES</b>		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
		n. Skin												
<b>13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</b>		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		p. Tendon												
<b>14. PROPRIETARY NAME(S)</b>		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
		r. Vascular Graft												
<b>15. OTHER INFORMATION</b>		s.												
		t.												
<b>16. COMMENTS</b>		u.												
		v.												

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<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>							11. HCT/Ps DESCRIBED IN 21 CFR 127.110	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
<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) East Tennessee Lions Eye Bank  201 W. Watauga Ave. Johnson City, Tennessee 37602  a. PHONE 865-305-9625 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3002689373) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps		Establishment Functions								
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<b>7. ENTER CORRECTIONS TO ITEM 6</b>		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
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		j. Pericardium										
a. E-MAIL		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		l. Sclera	X							X		
a. TYPED NAME Yvette Venters b. E-MAIL yventers@utmck.edu c. TITLE QA Director d. DATE 18-NOV-2015		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
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		v.										