

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: 3004125613	<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:22-DEC-2016 DISTRICT: New Orleans PRINTED BY FDA:28-DEC-2016
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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)								
<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>Types of HCT / Ps</b>	<b>Establishment Functions</b>											
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) DCI Donor Services dba Tennessee Donor Services (Chattanooga)  651 East Fourth Street, Suite 100 University Tower Chattanooga, Tennessee 37403  a. PHONE 423-756-5736 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone		X							X			
	b. Cartilage		X							X			
	c. Cornea		X							X			
	d. Dura Mater												
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	f. Fascia		X							X			
	g. Heart Valve		X							X			
	h. Ligament		X							X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium		X							X			
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	l. Sclera		X							X			
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	n. Skin		X							X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Tennessee Donor Services Attn: Sheryl R. Curtis 1600 Hayes Street Suite 300 Nashville, Tennessee 37203  a. PHONE 615-564-3624 EXT _____	p. Tendon		X							X			
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft		X							X			
<b>7. ENTER CORRECTIONS TO ITEM 6</b> a. PHONE _____ b. PHONE _____	s. Nerve Tissue		X							X			
	t.												
	u.												
	v.												
<b>8. U.S. AGENT</b>  a. E-MAIL _____													
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Sheryl R. Curtis b. E-MAIL scurtis@dcids.org c. TITLE Director of Quality and Compliance d. DATE 21-DEC-2016													