

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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3008808182	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:19-DEC-2011 DISTRICT: Cincinnati PRINTED BY FDA:13-JAN-2012
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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												
	<i>Establishment Functions</i>												
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Community Blood Center dba Community Tissue Services 2900 College Drive Kettering, Ohio 45420 a. PHONE 937-222-0228 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	X	X	X	X		
		b. Cartilage				X	X	X	X	X	X		
		c. Cornea											
		d. Dura Mater											
		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		f. Fascia				X	X	X	X	X	X		
5. ENTER CORRECTIONS TO ITEM 4		g. Heart Valve											
		h. Ligament				X	X	X	X	X			
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		j. Pericardium				X	X	X	X	X	X		
		k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
		l. Sclera											
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Community Blood Center dba Community Tissue Services Attn: David M. Smith, MD 349 South Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		n. Skin				X	X	X	X	X	X		
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
		p. Tendon				X	X	X	X	X	X		
8. U.S. AGENT a. E-MAIL _____		q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
		r. Vascular Graft											
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 18-DEC-2011		s. Parathyroid				X	X		X	X			
		t. Peritoneal Membrane				X	X	X	X	X	X		
		u.											
		v.											