

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: 0001570984	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:08-DEC-2011 DISTRICT: Cincinnati PRINTED BY FDA:15-DEC-2011
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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	Label	Distribute				
a. BLOOD FDA 2830 NO. FEI: 0001570984 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone	X	X	X		X	X	X	X	X			
	b. Cartilage	X	X	X		X	X	X	X	X			
	c. Cornea			X							X		
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 349 S. Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	d. Dura Mater												
	e. Embryo												
	f. Fascia	X	X	X		X	X	X	X	X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X	X						X			
	h. Ligament	X	X	X		X	X	X	X	X			
	i. Oocyte												
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 S. Main Street Dayton, Ohio 45402-2715 a. PHONE 937-461-3450 EXT 3610	j. Pericardium	X	X	X		X	X	X	X	X			
	k. Peripheral Blood Stem Cells	X	X	X	X	X	X	X	X	X			
	l. Sclera			X						X			
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	m. Semen												
	n. Skin	X	X	X		X	X	X	X	X			
	o. Somatic Cell Therapy Products	X			X							X	
8. U.S. AGENT a. E-MAIL	p. Tendon	X	X	X		X	X	X	X	X			
	q. Umbilical Cord Blood Stem Cells												
	r. Vascular Graft	X	X	X						X			
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME David M. Smith, MD b. E-MAIL dsmith@cbccts.org c. TITLE CEO d. DATE 07-DEC-2011	s. Parathyroid					X	X		X	X			
	t. Peritoneal Membrane	X	X	X		X	X	X	X	X			
	u.												
	v.												