

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> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 0001570984	<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	VALIDATION--FOR FDA USE ONLY 1 VALIDATED BY FDA:05-JAN-2010 DISTRICT: Cincinnati PRINTED BY FDA:23-FEB-2010
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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	X				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Community Blood Center dba Community Tissue Services 349 S. Main Street Dayton, Ohio 45402  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	b. Cartilage	X	X	X	X	X	X	X	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	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	X				
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) 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	X				
	k. Peripheral Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X	X	X	X	X	X	X	X	X	X			
	l. Sclera			X							X			
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous													
	n. Skin	X	X	X	X	X	X	X	X	X	X			
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic	X			X							X		
	p. Tendon	X	X	X	X	X	X	X	X	X				
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
8. U.S. AGENT  a. E-MAIL	r. Vascular Graft	X	X	X						X				
	s. Parathyroid					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 29-DEC-2009	t. Peritoneal Membrane	X	X	X	X	X	X	X	X	X				
	u.													
	v.													