

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) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001570969	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:03-DEC-2016 DISTRICT: Cincinnati PRINTED BY FDA:15-DEC-2016
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION															14. PROPRIETARY NAME(S)			
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps										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						
a. BLOOD FDA 2830 NO. <u>FEI: 0001570969</u> b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Establishment Functions																		
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute										
Hoxworth Blood Center, University of Cincinnati Medical Center 3130 Highland Ave Cincinnati, Ohio 45267-0055 a. PHONE 513-558-1200 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																		
	b. Cartilage																		
	c. Cornea																		
	d. Dura Mater																		
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																		
	f. Fascia																		
	g. Heart Valve																		
	h. Ligament																		
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																		
	j. Pericardium																		
	k. Peripheral Blood Stem <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X		X	X	X	X	X	X	X		X						
	l. Sclera																		
	m. Semen <input checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous							X					X	X					
	n. Skin																		
	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X		X	X	X	X	X	X	X		X						
	p. Tendon																		
	q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic				X	X	X	X	X	X	X		X						
	r. Vascular Graft																		
	s. Pancreatic Islet Cells - autologous				X	X			X	X	X								
	t. Therapeutic Cells	X	X		X	X	X	X	X	X	X		X						
	u.																		
	v.																		