

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
 (Field Establishment Identifier)
 FEI: 3008771780

2. REASON FOR SUBMISSION
 a. INITIAL REGISTRATION / LISTING
 b. ANNUAL REGISTRATION / LISTING
 c. CHANGE IN INFORMATION
 d. INACTIVE

VALIDATION--FOR FDA USE ONLY
 VALIDATED BY FDA:09-FEB-2011
 DISTRICT: Denver
 PRINTED BY FDA:09-FEB-2011

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	
			Recover	Screen	Test	Package	Process	Store	Label	Distribute									
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone																	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) University of Colorado Hospital Authority Clinical Laboratory-Microbiology Mailstop A-022 12401 East 17th Avenue Aurora, Colorado 80045		b. Cartilage																	
a. PHONE 720-848-7035 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input checked="" type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		c. Cornea																	
5. ENTER CORRECTIONS TO ITEM 4		d. Dura Mater																	
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) University of Colorado Hospital Authority Attn: Terri L. Ballard Clinical Laboratory-Microbiology Mailstop A-022 12401 East 17th Avenue Aurora, Colorado 80045		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
a. PHONE 720-848-7035 EXT _____ b. PHONE _____		f. Fascia																	
7. ENTER CORRECTIONS TO ITEM 6		g. Heart Valve																	
8. U.S. AGENT a. E-MAIL _____		h. Ligament																	
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Terri L. Ballard b. E-MAIL terri.ballard@uch.edu c. TITLE Chief Technologist d. DATE 28-SEP-2010		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 type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic							X							X		X	
		l. Sclera																	
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
		n. Skin																	
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
		p. Tendon																	
		q. Umbilical Cord Blood <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic							X							X		X	
		r. Vascular Graft																	
		s.																	
		t.																	
		u.																	
		v.																	