

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 <i>(Field Establishment Identifier)</i> FEI: 3007867618	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	1 VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:21-DEC-2010 DISTRICT: Denver PRINTED BY FDA:22-DEC-2010
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PART I - ESTABLISHMENT INFORMATION		PART II - PRODUCT INFORMATION									14. PROPRIETARY NAME(S)		
		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
3. OTHER FDA REGISTRATIONS		Establishment Functions									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
		Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. BLOOD FDA 2830 NO. _____							X	X	X	X			
b. DEVICES FDA 2891 NO. _____							X	X	X	X			
c. DRUG FDA 2656 NO. _____													
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)		a. Bone											
Bio Cell and Tissue Technologies 675 Arapeen Drive Salt Lake City, Utah 84108		b. Cartilage											
		c. Cornea											
		d. Dura Mater											
a. PHONE 801-554-3554 EXT _____		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)		f. Fascia						X	X	X	X		
c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY													
5. ENTER CORRECTIONS TO ITEM 4		g. Heart Valve											
		h. Ligament											
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)		i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
Bio Cell and Tissue Technologies Attn: Jan L. Pierce, MBA, CTBS 1762 Sunrise Park Drive Sandy, Utah 84093		j. Pericardium											
		k. Peripheral Blood Stem Cells	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		l. Sclera											
a. PHONE 801-554-3554 EXT _____		m. Semen	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous										
7. ENTER CORRECTIONS TO ITEM 6		n. Skin						X	X	X	X		
b. PHONE _____		o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
8. U.S. AGENT		p. Tendon						X	X	X	X		
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						X	X	X	X		
9. REPORTING OFFICIAL'S SIGNATURE		s.											
a. TYPED NAME Jan L. Pierce, MBA, CTBS b. E-MAIL jpierce280@msn.com c. TITLE President		t.											
		u.											
		v.											
d. DATE 06-DEC-2010													