

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: 3003447829	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:14-DEC-2016 DISTRICT: Denver PRINTED BY FDA:28-DEC-2016
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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											
	Establishment Functions											
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Statline 6400 S. Fiddler's Green Circle Suite 300 Greenwood Village, Colorado 80111 a. PHONE 303-691-3363 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone		X							X		
	b. Cartilage		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	
	g. Heart Valve			X							X	
	h. Ligament			X							X	
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	j. Pericardium			X							X	
5. ENTER CORRECTIONS TO ITEM 4	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	l. Sclera			X						X		
	m. Semen <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) Statline Attn: Donna Newman 6400 S. Fiddler's Green Circle Suite 300 Greenwood Village, Colorado 80111 a. PHONE 303-691-3363 EXT 2899	n. Skin			X						X		
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	p. Tendon			X						X		
7. ENTER CORRECTIONS TO ITEM 6	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	r. Vascular Graft			X						X		
8. U.S. AGENT a. E-MAIL	s.											
	t.											
	u.											
	v.											
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Donna Newman b. E-MAIL donna_newman@statline.org c. TITLE Manager, Quality Systems and Training d. DATE 13-DEC-2016												