

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 (Field Establishment Identifier) FEI: 3000204058	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 1 VALIDATED BY FDA:28-JAN-2009 DISTRICT: Los Angeles PRINTED BY FDA:30-JAN-2009
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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				
	<i>Establishment Functions</i>															
	<i>Types of HCT / Ps</i>															
	Recover	Screen	Test	Package	Process	Store	Label	Distribute								
a. BLOOD FDA 2830 NO. FEI: 0002077975 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____																
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Blood Systems, Inc. Blood Systems Laboratories 2424 West Erie Drive Tempe, Arizona 85252 a. PHONE 602-343-7000 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		X							X						
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous		X							X						
	f. Fascia		X							X						
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X							X						
	h. Ligament		X							X						
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous		X							X						
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Blood Systems, Inc. Attn: Mary Beth Bassett 6210 East Oak St. Scottsdale, Arizona 85257 a. PHONE 480-946-4201 EXT _____	j. Pericardium		X							X						
	k. Peripheral Blood Stem Cells <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				
	l. Sclera		X							X						
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous		X							X						
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	n. Skin		X							X						
	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic		X							X						
8. U.S. AGENT a. E-MAIL _____	p. Tendon		X							X						
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic		X		X	X	X	X	X	X		X				
	r. Vascular Graft		X							X						
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Mary Beth Bassett b. E-MAIL mbassett@bloodsystems.org c. TITLE VP QM / RA d. DATE 05-JAN-2009	s.															
	t.															
	u.															
	v.															