

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3004521286	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:29-NOV-2017 DISTRICT: New Jersey PRINTED BY FDA:27-JAN-2018
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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)							
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>											
	<b>Types of HCT / Ps</b>	<b>Establishment Functions</b>										
		Recover	Screen	Test	Package	Process	Store	Label	Distribute			
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) HLA Registry  102 Chestnut Ridge Road Montvale, New Jersey 07645  a. PHONE 201-444-3900 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
	l. Sclera											
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	n. Skin											
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Blood Systems, Inc. Attn: Gina Ramirez 6210 East Oak Street P.O.Box 1867 Scottsdale, Arizona 85252-1867  a. PHONE 303-363-2221 EXT _____	p. Tendon											
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
<b>7. ENTER CORRECTIONS TO ITEM 6</b> a. PHONE _____ b. PHONE _____	r. Vascular Graft											
<b>8. U.S. AGENT</b>  a. E-MAIL _____	s. Therapeutic Cells	X	X					X	X		X	
	t.											
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Gina Ramirez b. E-MAIL gramirez@bloodsystems.org c. TITLE Regulatory Manager d. DATE 29-NOV-2017	u.											
	v.											