

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: 1000307669	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY 1 VALIDATED BY FDA:29-JUN-2010 DISTRICT: Florida PRINTED BY FDA:29-JUN-2010
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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											
	Types of HCT / PS	Establishment Functions										
		Recover	Screen	Test	Package	Process	Store	Label	Distribute			
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone		X							X		
	b. Cartilage		X							X		
	c. Cornea		X							X		
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Southeast Tissue Alliance, Inc. 6241 NW 23rd St., Suite 400 Gainesville, Florida 32653 a. PHONE 352-248-2114 EXT 6621 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	d. Dura Mater											
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	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 type="checkbox"/> Anonymous											
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Southeast Tissue Alliance, Inc. Attn: Elizabeth A. Crews, MT(ASCP),CTBS 6241 NW 23rd St., Suite 400 Gainesville, Florida 32653 a. PHONE 352-416-6618 EXT _____ b. PHONE _____	j. Pericardium		X							X		
	k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	l. Sclera		X							X		
7. ENTER CORRECTIONS TO ITEM 6	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	n. Skin		X							X		
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
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 type="checkbox"/> Allogeneic											
	r. Vascular Graft		X							X		
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Elizabeth A. Crews, MT(ASCP),CTBS b. E-MAIL ecrews@donorcare.org c. TITLE Quality Assurance Manager d. DATE 25-JUN-2010	s. Amniotic Membrane		X							X		
	t. Nerve Tissue		X							X		
	u. Placenta		X							X		
	v. Amniotic Fluid		X							X		