

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 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:09-DEC-2011 DISTRICT: Florida PRINTED BY FDA:15-DEC-2011
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION													
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	14. PROPRIETARY NAME(S)	Establishment Functions								
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Types of HCT / Ps					Recover	Screen	Test	Package	Process	Store	Label	Distribute	
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> 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	a. Bone <input type="checkbox"/> SIP b. Cartilage <input type="checkbox"/> Directed c. Cornea <input type="checkbox"/> Anonymous d. Dura Mater e. Embryo <input type="checkbox"/> SIP f. Fascia <input type="checkbox"/> Directed g. Heart Valve <input type="checkbox"/> Anonymous h. Ligament i. Oocyte <input type="checkbox"/> SIP j. Pericardium <input type="checkbox"/> Directed k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous l. Sclera <input type="checkbox"/> Family Related m. Semen <input type="checkbox"/> Allogeneic n. Skin o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous p. Tendon <input type="checkbox"/> Family Related q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Allogeneic r. Vascular Graft	X	X	X	X	X	X	X	X	X	X	X		
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve h. Ligament i. Oocyte j. Pericardium k. Peripheral Blood Stem Cells l. Sclera m. Semen n. Skin o. Somatic Cell Therapy Products p. Tendon q. Umbilical Cord Blood Stem Cells r. Vascular Graft	X	X	X	X	X	X	X	X	X	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> Southeast Tissue Alliance, Inc. Attn: Lawrence Hopkins 6241 NW 23rd St., Suite 400 Gainesville, Florida 32653 a. PHONE 352-416-6641 EXT _____ b. PHONE _____	s. Amniotic Membrane t. Nerve Tissue u. Placenta v. Amniotic Fluid	X	X	X	X	X	X	X	X	X	X	X		
7. ENTER CORRECTIONS TO ITEM 6	s. Amniotic Membrane t. Nerve Tissue u. Placenta v. Amniotic Fluid	X	X	X	X	X	X	X	X	X	X	X		
8. U.S. AGENT a. E-MAIL _____	s. Amniotic Membrane t. Nerve Tissue u. Placenta v. Amniotic Fluid	X	X	X	X	X	X	X	X	X	X	X		
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Lawrence Hopkins b. E-MAIL lagle@donorcare.org c. TITLE Chief Executive Officer d. DATE 08-DEC-2011	s. Amniotic Membrane t. Nerve Tissue u. Placenta v. Amniotic Fluid	X	X	X	X	X	X	X	X	X	X	X		