

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: 3003567064	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. 1621 Physicians Drive Tallahassee, Florida 32308 a. PHONE 850-656-4960 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone <input checked="" type="checkbox"/> X b. Cartilage <input checked="" type="checkbox"/> X c. Cornea d. Dura Mater e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous f. Fascia <input checked="" type="checkbox"/> X						X	X	X				
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve <input checked="" type="checkbox"/> X h. Ligament <input checked="" type="checkbox"/> X i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous j. Pericardium <input checked="" type="checkbox"/> X k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic l. Sclera m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous n. Skin <input checked="" type="checkbox"/> 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, CTBS 6241 NW 23rd, St., Suite 400 Gainesville, Florida 32653 a. PHONE 352-416-6641 EXT _____ b. PHONE _____	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic p. Tendon <input checked="" type="checkbox"/> X q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic r. Vascular Graft <input checked="" type="checkbox"/> X						X	X	X				
7. ENTER CORRECTIONS TO ITEM 6	s. Amniotic Membrane <input checked="" type="checkbox"/> X t. Nerve Tissue <input checked="" type="checkbox"/> X u. Placenta <input checked="" type="checkbox"/> X v. Amniotic Fluid <input checked="" type="checkbox"/> X						X	X	X				
8. U.S. AGENT a. E-MAIL _____													
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Lawrence Hopkins, CTBS b. E-MAIL lagle@donorcare.org c. TITLE Chief Executive Officer d. DATE 08-DEC-2011													