

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: 3003567004	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 VALIDATED BY FDA:07-DEC-2009 DISTRICT: Florida PRINTED BY FDA:18-DEC-2009
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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 a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2" style="width:30%;">Types of HCT / Ps</th> <th colspan="8" style="text-align: center;">Establishment Functions</th> <th rowspan="2">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> </table>	Types of HCT / Ps	Establishment Functions								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)	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
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4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Southeast Tissue Alliance, Inc. 1901 NW 67th Place Bay D Gainesville, Florida 32653 a. PHONE 352-271-7300 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"/> Recover b. Cartilage <input checked="" type="checkbox"/> Recover 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"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute g. Heart Valve <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute h. Ligament <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous j. Pericardium <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute k. Peripheral Blood Stem <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"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic p. Tendon <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute 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"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute																									
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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: Elizabeth A. Crews, MT (ASCP), CTBS 6241 NW 23rd. St. Suite 400 Gainesville, Florida 32653 a. PHONE 352-416-6618 EXT _____ b. PHONE _____	s. Nerve Tissue <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute t. Placenta <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute u. v.																									
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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 04-DEC-2009	s. Nerve Tissue <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute t. Placenta <input checked="" type="checkbox"/> Recover <input checked="" type="checkbox"/> Store <input checked="" type="checkbox"/> Label <input checked="" type="checkbox"/> Distribute u. v.																									