

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: 3003567027	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:09-DEC-2011 DISTRICT: Florida PRINTED BY FDA:15-DEC-2011
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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">Recover</th> <th rowspan="2">Screen</th> <th rowspan="2">Test</th> <th rowspan="2">Package</th> <th rowspan="2">Process</th> <th rowspan="2">Store</th> <th rowspan="2">Label</th> <th rowspan="2">Distribute</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								Recover	Screen	Test	Package	Process	Store	Label	Distribute	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
Types of HCT / Ps	Establishment Functions								Recover	Screen									Test	Package	Process	Store	Label	Distribute						
	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. 8535 Baymeadows Road Suite 40 Jacksonville, Florida 32256 a. PHONE 904-419-5081 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X																												
	b. Cartilage	X																												
	c. Cornea																													
	d. Dura Mater																													
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																													
	f. Fascia	X													X	X														
	g. Heart Valve	X													X	X														
	h. Ligament	X													X	X														
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																													
	j. Pericardium	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 _____	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	X													X	X														
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																													
	p. Tendon	X													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	X														
	s. Nerve Tissue	X													X	X														
	t. Placenta	X													X	X														
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Lawrence Hopkins, CTBS b. E-MAIL lagle@donorcare.org c. TITLE Chief Executive Officer	u.																													
	v.																													
	d. DATE 08-DEC-2011																													