

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: 3003103882	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:27-NOV-2009 DISTRICT: Florida PRINTED BY FDA:02-DEC-2009
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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> Florida Tissue Services, Inc. 3298 Summit Blvd Suite 29 Pensacola, Florida 32503 a. PHONE 850-471-1672 EXT 3402 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"/> SIP b. Cartilage <input type="checkbox"/> Directed c. Cornea <input type="checkbox"/> Anonymous d. Dura Mater e. Embryo <input type="checkbox"/> Directed f. Fascia <input type="checkbox"/> Anonymous g. Heart Valve <input type="checkbox"/> Anonymous h. Ligament <input type="checkbox"/> Anonymous i. Oocyte <input type="checkbox"/> Directed j. Pericardium <input type="checkbox"/> Anonymous k. Peripheral Blood Stem <input type="checkbox"/> Autologous l. Sclera <input type="checkbox"/> Family Related m. Semen <input type="checkbox"/> Allogeneic n. Skin <input type="checkbox"/> Anonymous o. Somatic Cell Therapy Products <input type="checkbox"/> Allogeneic p. Tendon <input type="checkbox"/> Allogeneic q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Family Related r. Vascular Graft <input type="checkbox"/> Allogeneic	X	X	X	X	X	X	X	X	X	X		
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve <input type="checkbox"/> Anonymous h. Ligament <input type="checkbox"/> Anonymous i. Oocyte <input type="checkbox"/> Directed j. Pericardium <input type="checkbox"/> Anonymous k. Peripheral Blood Stem <input type="checkbox"/> Autologous l. Sclera <input type="checkbox"/> Family Related m. Semen <input type="checkbox"/> Allogeneic n. Skin <input type="checkbox"/> Anonymous o. Somatic Cell Therapy Products <input type="checkbox"/> Allogeneic p. Tendon <input type="checkbox"/> Allogeneic q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Family Related r. Vascular Graft <input type="checkbox"/> Allogeneic	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> Florida Tissue Services, Inc. c/o LifeNet Health Attn: Michael Plew 1864 Concert Drive Virginia Beach, Virginia 23453 a. PHONE 757-464-4761 EXT 4648	s. Cardiac Tissue - non-valved t. Nerve Tissue u. v.	X	X	X	X	X	X	X	X	X	X		
7. ENTER CORRECTIONS TO ITEM 6	s. Cardiac Tissue - non-valved t. Nerve Tissue u. v.	X	X	X	X	X	X	X	X	X	X		
8. U.S. AGENT a. E-MAIL	s. Cardiac Tissue - non-valved t. Nerve Tissue u. v.	X	X	X	X	X	X	X	X	X	X		
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Michael Plew b. E-MAIL michael_plew@lifenethealth.org c. TITLE VP, Quality & Regulatory Compliance d. DATE 25-NOV-2009	s. Cardiac Tissue - non-valved t. Nerve Tissue u. v.	X	X	X	X	X	X	X	X	X	X		