

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: 3004468602	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:02-DEC-2011 DISTRICT: Florida PRINTED BY FDA:15-DEC-2011
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION														14. PROPRIETARY NAME(S)		
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					
	<i>Establishment Functions</i>																
		<i>Types of HCT / Ps</i>	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> LifeNet Health of Florida 12276 San Jose Blvd Suite 706 Jacksonville, Florida 32223 a. PHONE 904-262-7711 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		a. Bone	X			X				X		X					
		b. Cartilage	X			X				X		X					
		c. Cornea	X			X				X		X					
		d. Dura Mater															
		e. Embryo	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
		f. Fascia	X			X				X		X					
		g. Heart Valve	X			X				X		X					
		h. Ligament	X			X				X		X					
		i. Oocyte	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
		j. Pericardium	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> LifeNet Health of Florida c/o LifeNet Health Attn: Michael Plew 1864 Concert Drive Virginia Beach, Virginia 23453 a. PHONE 757-464-4761 EXT 4648		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		X					
		o. Somatic Cell Therapy Products	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
		p. Tendon	X			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		X					
		s. Cardiac Tissue - non-valved	X			X				X		X					
		t. Nerve Tissue	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 01-DEC-2011		u. Placenta	X								X						
		v.															