

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3003452735	<b>2. REASON FOR SUBMISSION</b> 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: Baltimore PRINTED BY FDA:02-DEC-2009
--	--	--	---

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
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> LifeNet Health 1948 Franklin Rd., Suite A 100 Roanoke, Virginia 24014  a. PHONE 540-342-7133 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3005064037) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone b. Cartilage c. Cornea d. Dura Mater e. Embryo f. Fascia g. Heart Valve h. Ligament i. Oocyte j. Pericardium k. Peripheral Blood Stem l. Sclera m. Semen n. Skin o. Somatic Cell Therapy Products p. Tendon q. Umbilical Cord Blood Stem Cells r. Vascular Graft s. Cardiac Tissue - non-valved t. Nerve Tissue u. v.												
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> LifeNet Health Attn: Michael A. Plew 1864 Concert Drive Virginia Beach, Virginia 23453  a. PHONE 757-464-4761 EXT 4648	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
<b>8. U.S. AGENT</b>  a. E-MAIL _____	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Michael A. Plew b. E-MAIL michael_plew@lifenethealth.org c. TITLE VP, Quality and Regulatory Compliance d. DATE 25-NOV-2009													