

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> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3009672666	<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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:17-NOV-2017 DISTRICT: Seattle PRINTED BY FDA:27-JAN-2018
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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	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps													
	Types of HCT / Ps	Establishment Functions												
		Recover	Screen	Test	Package	Process	Store	Label	Distribute					
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) LifeNet Health Northwest, LLC  501 SW 39th Street Renton, Washington 98057  a. PHONE 425-981-8900 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	X	X	X	X	X		
	b. Cartilage	X			X	X	X	X	X	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	X				
	g. Heart Valve	X			X	X	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				
<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) LifeNet Health Attn: Michael Plew 1864 Concert Drive Virginia Beach, Virginia 23453  a. PHONE 757-464-4761 EXT 4648	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	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	X			
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
	r. Vascular Graft	X			X	X	X	X	X	X				
	s. Cardiac Tissue - non-valved	X			X	X	X	X	X	X	X			
	t.													
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____	u.													
	v.													
<b>8. U.S. AGENT</b>  a. E-MAIL _____														
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Michael Plew b. E-MAIL michael_plew@lifenethealth.org c. TITLE SVP, Global Quality & Regulatory Compliance d. DATE 17-NOV-2017														