

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 1 VALIDATED BY FDA:02-DEC-2011 DISTRICT: Baltimore 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)																																																																																																																																																																																																																																																																								
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b> <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">11. HCT/PS DESCRIBED IN 21 CFR 1271.10</th> <th rowspan="2">12. HCT/PS REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</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								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)	Recover	Screen	Test	Package	Process	Store	Label	Distribute																																																																																																																																																																																																																																																			
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<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	<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td>a. Bone</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>b. Cartilage</td> <td style="text-align: center;">X</td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> <td style="text-align: center;">X</td> <td></td> <td></td> <td></td> </tr> <tr> <td>c. 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**5. ENTER CORRECTIONS TO ITEM 4**					
**6. MAILING ADDRESS OF REPORTING OFFICIAL** *(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					
**7. ENTER CORRECTIONS TO ITEM 6** b. PHONE \_\_\_\_\_					
**8. U.S. AGENT**    a. E-MAIL \_\_\_\_\_					
**9. REPORTING OFFICIAL'S SIGNATURE**    a. TYPED NAME Michael Plew   b. E-MAIL michael\_plew@lifenethealth.org   c. TITLE VP, Quality and Regulatory Compliance d. DATE 01-DEC-2011					