See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 8/31/10

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)

(See reverse side for instructions)

1. REGISTRATION NUMBER
(Field Establishment Identifier)

FEI: 1000512996

2. REASON FOR SUBMISSION
- a. ☐ INITIAL REGISTRATION / LISTING
- b. ☒ ANNUAL REGISTRATION / LISTING
- c. ☐ CHANGE IN INFORMATION
- d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:27-NOV-2009
DISTRICT: Baltimore
PRINTED BY FDA:02-DEC-2009

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. _____

c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

LifeNet Health
5809 Ward Ct.
Virginia Beach, Virginia 23455

a. PHONE 757-464-4761 EXT 4648

b. ☐ SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO._____

c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

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 A. 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 A. Plew

b. E-MAIL michael_plew@lifenethealth.org

c. TITLE VP, Quality and Regulatory Compliance d. DATE 25-NOV-2009

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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				
a. Bone	X			X	X	X	X		X			OsteoCleanse
b. Cartilage	X			X		X	X		X			
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia	X			X		X	X		X			
g. Heart Valve	X			X	X	X	X		X			CardioGraft
h. Ligament	X			X		X	X		X			
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium	X			X		X	X		X			
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin	X			X		X	X		X			
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon	X			X		X	X		X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft	X			X	X	X	X		X			AngioGraft
s. Cardiac Tissue - non-valved	X			X	X	X	X		X	X		**CardioGraft**
t. Nerve Tissue	X			X	X	X	X		X			**Avance**
u.												
v.												

FORM FDA 3356 (4/08)