# LifeNet Health of Florida FDA Registration

***Is LifeNet Health of Florida registered with FDA?***
Yes. LifeNet Health of Florida is considered to be registered with FDA through LifeNet Health's corporate FDA registration (attached).

***Why were the individual Florida facility registrations for Pensacola and Jacksonville discontinued?***
They were discontinued, because FDA informed us that facilities used to store recovery supplies are exempt from registering unless tissue is stored there as well. Recovered tissues are sent immediately to our registered locations for storage and processing.

***What regulation describes this registration exemption?***
21 C.F.R. § 1271.15(f): *You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.*

See Instructions for OMB Statement

FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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**
(FDA Establishment Identifier)

**FEI:** 3005064037

**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-2013
DISTRICT: Baltimore
PRINTED BY FDA:09-DEC-2013

## PART I - ESTABLISHMENT INFORMATION

**3. OTHER FDA REGISTRATIONS**

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. FEI: 3005064037

c. DRUG FDA 2656 NO. _____

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

LifeNet Health

1864 Concert Drive
Virginia Beach, Virginia 23453

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 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 26-NOV-2013

## PART II - PRODUCT INFORMATION

**10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps**

| Types of HCT / Ps | Establishment Functions: Recover | Screen | Test | Package | Process | Store | Label | Distribute | 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) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| a. Bone | | X | X | X | X | X | X | X | X | X | | *** See full text on next page |
| b. Cartilage | | X | X | X | X | X | X | X | X | | | FlexiGraft |
| c. Cornea | | | X | | | | | | X | | | |
| d. Dura Mater | | | | | | | | | | | | |
| e. Embryo ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| f. Fascia | | X | X | X | X | X | X | X | X | | | ReadiGraft, OraGraft |
| g. Heart Valve | | X | X | | | X | X | X | X | | | CardioGraft |
| h. Ligament | | X | X | X | X | X | X | X | X | | | FlexiGraft |
| i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| j. Pericardium | | X | X | X | X | X | X | X | X | | | ReadiGraft |
| k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| l. Sclera | | | X | | | | | | X | | | |
| m. Semen ☐ SIP ☐ Directed ☐ Anonymous | | | | | | | | | | | | |
| n. Skin | | X | X | | | X | X | X | X | | | *** See full text on next page |
| o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic | | | | | | | | | | | | |
| p. Tendon | | X | X | X | X | X | X | X | X | X | | FlexiGraft, GraftLink |
| q. Umbilical Cord Blood ☐ 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 | | | |
| u. | | | | | | | | | | | | |
| v. | | | | | | | | | | | | |

**FORM FDA 3356 (11/11)**

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**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

| | |
|---|---|
| a. Bone | MatriGraft,OraGraft, ReadiGraft,VertiGraft,Optium, I/C Graft Chambers, Ossiflex, AlloOss |
| n. Skin | ReadiGraft, TheraSkin, DermACELL, OrACELL, Arthroflex |