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| 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) <i>(See reverse side for instructions)</i> | 1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3005064037 | 2. REASON FOR SUBMISSION 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:27-NOV-2009 DISTRICT: Baltimore PRINTED BY FDA:02-DEC-2009 |
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| PART I - ESTABLISHMENT INFORMATION | PART II - PRODUCT INFORMATION | | | | | | | | | | | | | | 14. PROPRIETARY NAME(S) |
|---|---|--|---------|--------|------|---------|---------|-------|-------|--|---|---|--------------------------------|--------------------------------|-------------------------|
| 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 | | | |
| | <i>Establishment Functions</i> | | | | | | | | | | | | | | |
| | | Types of HCT / Ps | Recover | Screen | Test | Package | Process | Store | Label | Distribute | | | | | |
| 4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> LifeNet Health 1864 Concert Drive Virginia Beach, Virginia 23453 a. PHONE 757-464-4761 EXT 4648 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 | | *** See full text on next page | |
| | | b. Cartilage | | X | X | X | X | X | X | X | X | X | | FlexiGraft | |
| 5. ENTER CORRECTIONS TO ITEM 4 | | c. Cornea | | | X | | | | | | | X | | | |
| | | d. Dura Mater | | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL <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 | | e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | |
| | | f. Fascia | | X | X | X | X | X | X | X | X | X | | ReadiGraft, OraGraft | |
| 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE | | g. Heart Valve | | X | X | X | | X | X | X | X | | CardioGraft | | |
| | | h. Ligament | | X | X | X | X | X | X | X | X | | FlexiGraft | | |
| 8. U.S. AGENT a. E-MAIL | | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | |
| | | j. Pericardium | | X | X | X | X | X | X | X | X | X | | ReadiGraft | |
| 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 | | k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | |
| | | l. Sclera | | | X | | | | | | | X | | | |
| | | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | |
| | | n. Skin | | X | X | X | | X | X | X | X | | *** See full text on next page | | |
| | | 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 | X | X | X | | FlexiGraft | | |
| | | q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | |
| | | r. Vascular Graft | | X | X | X | | X | X | X | X | | AngioGraft | | |
| | | s. Cardiac Tissue - non-valved | | X | X | X | | X | X | X | X | X | CardioGraft | | |
| | | t. Nerve Tissue | | X | X | | | | | | X | | | | |
| | | u. | | | | | | | | | | | | | |
| | | v. | | | | | | | | | | | | | |

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)

2

FEI: 3005064037

ADDITIONAL INFORMATION:

Proprietary Name(s):

- a. Bone OsteoBiologics, OsteoCleanse, MatriGraft, OraGraft,
 ReadiGraft, VertiGraft, Optium, I/C Graft Chambers
- n. Skin ReadiGraft, TheraSkin, DermAcell, OrAcell, Arthroflex