

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:04-DEC-2011 DISTRICT: Baltimore PRINTED BY FDA:15-DEC-2011
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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>														
	Recover	Screen	Test	Package	Process	Store	Label	Distribute							
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3005064037 c. DRUG FDA 2656 NO. _____															
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 pag		
	b. Cartilage		X	X	X	X	X	X	X	X			FlexiGraft		
	c. Cornea			X							X				
	d. Dura Mater														
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	f. Fascia		X	X	X	X	X	X	X	X				ReadiGraft, OraGraft	
	g. Heart Valve		X	X	X		X	X	X	X				CardioGraft	
	h. Ligament		X	X	X	X	X	X	X	X				FlexiGraft	
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	j. Pericardium		X	X	X	X	X	X	X	X				ReadiGraft	
k. Peripheral Blood Stem Cells <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															
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin		X	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														
8. U.S. AGENT a. E-MAIL	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		
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 02-DEC-2011	s. Cardiac Tissue - non-valved		X	X	X		X	X	X	X			CardioGraft		
	t. Nerve Tissue		X	X						X					
	u.														
	v.														

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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

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ADDITIONAL INFORMATION:

Proprietary Name(s):

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