

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. <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 VALIDATED BY FDA:17-NOV-2017 DISTRICT: Baltimore PRINTED BY FDA:27-JAN-2018
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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)				
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps																	
	Types of HCT / Ps	Establishment Functions								Recover					Screen	Test	Package	Process
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3005064037 c. DRUG FDA 2656 NO. _____		a. Bone			X	X	X	X	X		X	X	X	X				
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. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	b. Cartilage			X	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	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	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	X	X					ReadiGraft
	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																		
5. ENTER CORRECTIONS TO ITEM 4	n. Skin			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																	
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	p. Tendon			X	X	X	X	X	X	X	X	X	X					*** See full text on next page
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
	r. Vascular Graft			X	X				X	X	X	X	X					AngioGraft
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	s. Cardiac Tissue - non-valved			X	X				X	X	X	X	X					CardioGraft, CardioGraft-MC
	t.																	
	u.																	
	v.																	
	8. U.S. AGENT																	
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Michael Plew b. E-MAIL michael_plew@lifenethealth.org c. TITLE SVP,Global Quality&Regulatory Complianc d. DATE 17-NOV-2017																		

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

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ADDITIONAL INFORMATION:

Bone proprietary names (cont): VESUVIUS, BIO AVS, Trinnect,BIO
Chips, BIO Wedge, BIO Shaft, MatriSPINE, FlexiGraft, ReadiGraft
BLX

Proprietary Name(s):

- a. Bone ViviGen, ViviGen Formable, PliaFX,
 MatriGraft,OraGraft,ReadiGraft,VertiGraft,Optium,I/C
 Graft Chamber, AlloOss, VIKOS
- n. Skin ReadiGraft, TheraSkin, DermACELL, DermACELL
 AWM, OrACELL, ArthroFLEX, ArthroFLEX
 BioWasher
- p. Tendon FlexiGraft, GraftLink, GraftLink TS, KinetiGraft