

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 DESCRIBED IN 21 CFR 1271.10	FEI: 3005064037	Other FDA Registrations: Blood: Devices: FEI: 3005064037 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2019 Last Registration Receipt Date: 11/21/2018 Summary Report Print Date: 12/19/2018
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Legal Name and Location: LifeNet Health 1864 Concert Drive Virginia Beach, Virginia 23453 USA Phone: 757-464-4761 Ext.: 4648	Reporting Official: Michael Plew, SVP,Global Quality&Regulatory Compliance 1864 Concert Drive Virginia Beach, Virginia 23453 USA Phone: 757-464-4761 Ext. 4648 michael_plew@lifenethealth.org	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: No Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel			X	X				X	X	X		AngioGraft
Bone			X	X	X	X	X	X	X	X		***See full text on next page.
Cardiac Tissue - non-valved			X	X				X	X	X		CardioGraft
Cartilage			X	X	X	X	X	X	X	X		FlexiGraft
Cornea				X								
Dura Mater												
Embryo												
Fascia			X	X	X	X	X	X	X	X		ReadiGraft, OraGraft
Heart Valve			X	X				X	X	X		CardioGraft
HPC Apheresis												
HPC Cord Blood												
Ligament			X	X	X	X	X	X	X	X		FlexiGraft
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium			X	X	X	X	X	X	X	X		ReadiGraft
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera				X								
Semen												
Skin			X	X				X	X	X		***See full text on next page.
Tendon			X	X	X	X	X	X	X	X		FlexiGraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Bone proprietary names (cont): Straumann Allograft Ring, BIO AVS, Trinnect,BIO Chips, BIO Wedge, BIO Shaft, MatriSPINE, FlexiGraft, Readigraft BLX

Proprietary Name(s): Bone ViviGen, ViviGen Formable, PliAFX Prime, PliAFX Strip, SymALIGN, MatriGraft,OraGraft,ReadiGraft,VertiGraft AlloOss,VIKOS
Skin Readigraft, TheraSkin, DermACELL, DermACELL AWM, OrACELL, ArthroFLEX, ArthroFLEX BioWasher