

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,          TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS          DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3005381997	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 3005381997 <b>Drugs:</b>	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/17/2023 Summary Report Print Date: 12/01/2023
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<b>Legal Name and Location:</b>  LifeNet Health 5733 Bayside Road Suite 104  Virginia Beach, Virginia 23455 USA  Phone: 757-464-4761 <b>Ext.:</b> 4648	<b>Reporting Official:</b>  Michael Plew, SVP, Global Quality & Regulatory Compliance 1864 Concert Drive Attn: Mike Plew Virginia Beach, Virginia 23453 USA Phone: 757-464-4761 Ext. 4648 michael_plew@lifenethealth.org	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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					X	X	X	X				Matrion, AmnioExcite, Biolieve
Blood Vessel					X	X	X	X	X			AngioGraft, Nexeon AVX
Bone					X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved					X	X	X	X	X			CardioGraft
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia					X	X	X	X				
Heart Valve					X	X	X	X	X			CardioGraft
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					X	X	X	X				***See full text on next page.
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** No additional information provided.

<b>Proprietary Name(s):</b>	Bone	PliaFX Prime, PliaFX Strip, PliaFX PAK, OraGraft, OraGRAFT Prime, OraGRAFT Endure, Osseofiber, OsseoFiber-PLUS, Readigraft, Readigraft BLX, FlexiGraft, VESUVIUS, Bio DBM, BIO Expand, Straumann Allograft, Salvin Bulk, Neodent Allograft, Optium 100
	Skin	DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX BioWasher, OrACELL, Straumann Allograft, Stryker CMF

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Legal Name:

LifeNet Health