

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: 2026 Last Registration Receipt Date: 11/21/2025 Summary Report Print Date: 12/01/2025			
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 Attn: Mike Plew 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)).			
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			***See full text on next page.	
Blood Vessel				X		X							
Bone				X	X	X	X	X	X			***See full text on next page.	
Cardiac Tissue - non-valved				X		X							
Cartilage				X	X	X	X	X	X			FlexiGraft	
Cornea				X									
Dura Mater													
Embryo													
Fascia				X	X	X	X	X	X			***See full text on next page.	
Heart Valve				X		X							
HPC Apheresis													
HPC Cord Blood													
Ligament				X	X	X	X	X	X			FlexiGraft	
Nerve Tissue													
Oocyte													
Ovarian Tissue													
Pancreatic Islet Cells - autologous													
Parathyroid													
Pericardium				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			FlexiGraft	
Testicular Tissue													
Tooth Pulp													
Umbilical Cord Tissue													

Additional Information: No additional information provided.

Proprietary Name(s):	Amniotic Membrane	Matrion, AmnioExcite, Biolieve, OraMatrix
	Bone	ViviGen, ViviGen Formable, OraGEN, PliaFX Prime, PliaFX Strip, PliaFX PAK,,SymALIGN, MatriGraft, OraGraft, Readigraft, VertiGraft, AlloOss, AlloOss Block Graft, VIKOS, Straumann Allograft, BIO AVS, Trinnect, BIO Chips, BIO Wedge, BIO Shaft, MatriSPINE, FlexiGraft, Readigraft BLX, OraGraft, OraGRAFT Prime, OraGRAFT Endure, OsseoFiber, OsseoFiber-PLUS, Neodent Allograft, Optium 100,PRO-SPEC
	Fascia	Readigraft, OraGraft, Perio Fascia Lata
	Skin	Readigraft, TheraSkin, Dermacell, Dermacell AWM, Dermacell Porous, OrACELL ArthroFLEX, ArthroFLEX BioWasher, Straumann Allograft

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