

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: 3015724777	Other FDA Registrations: Blood: Devices: FEI: 3015724777 Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 11/18/2022 Summary Report Print Date: 12/01/2022
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Legal Name and Location: LifeNet Health 845 Airtech Parkway Suite 198 Plainfield, Indiana 46168 USA Phone: 317-754-3000 Ext.:	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							X	X	X			Matrion, AmnioExcite, Biolieve
Blood Vessel							X	X	X			Nexeon AVX
Bone							X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage							X	X	X			Flexigraft
Cornea												
Dura Mater												
Embryo												
Fascia							X	X	X			***See full text on next page.
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							X	X	X			FlexiGraft
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							X	X	X			ReadiGraft
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X	X	X			***See full text on next page.
Tendon							X	X	X			FlexiGraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s): Bone	ViviGen, ViviGen Formable, OraGen, PliaFX Prime, PliaFX Strip, PliaFX PAK, SymALIGN, MatriGraft, OraGraft, Readigraft, VertiGraft, AlloOss, AlloOss Block Graft, VIKOS, Straumann Allograft Ring, 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
Fascia	Readigraft, OraGraft, Perio Fascia Lata
Skin	Readigraft, DermACELL, DermACELL AWM, OrACELL, ArthroFLEX, ArthroFLEX BioWasher, TheraSkin, Straumann Allograft

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