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:

Devices:FEI: 3015724777

Drugs:

Blood:

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 845 Airtech Parkway Suite 198

Plainfield, Indiana 46168 USA

Testicular Tissue Tooth Pulp **Umbilical Cord Tissue**

Phone: 317-754-3000

Reporting Official:

Michael Plew, SVP, Global Quality&Regulatory Compliance

1864 Concert Drive Attn: Mike Plew

Virginia Beach, Virginia 23453

Phone: 757-464-4761 Ext. 4648 michael_plew@lifenethealth.org

Satellite Recovery Establishment:

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)).

No

Ext.: Establishment Functions Date of Date of Proprietary Name(s) Donor Type(s) HCT/P(s) Screen Donor Testina Package Process Store Label Distribute Discontinuance Resumption ***See full text on next page. Amniotic Membrane Χ Χ Х Nexeon Blood Vessel Χ Χ Χ Χ Χ ***See full text on next page. Bone Χ Cardiac Tissue - non-valved Cartilage Χ Χ Χ Flexigraft Cornea Dura Mater Embryo ***See full text on next page. Fascia Χ Χ Χ Heart Valve **HPC Apheresis** HPC Cord Blood Χ Х FlexiGraft Ligament Х Nerve Tissue Oocyte Ovarian Tissue Pancreatic Islet Cells - autologous Parathyroid ReadiGraft Pericardium Χ Х Х Peripheral Blood Mononuclear Cells Peritoneal Membrane Sclera Semen ***See full text on next page. Skin Χ Х Х Tendon Χ Х Χ FlexiGraft

Legal Name: LifeNet Health 3015724777 FEI:

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 Ring, Straumann Allograft, BlO AVS, Trinnect, BlO Chips, BlO Wedge, BlO 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, Dermacell, Dermacell AWM, Dermacell Porous, OrACELL, ArthroFLEX, ArthroFLEX BioWasher, TheraSkin, Straumann Allograft, ReadiGraft Burn Skin