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: 3005381997

Other FDA Registrations: Blood:

Devices:FEI: 3005381997

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2021 Last Registration Receipt Date: 11/17/2020 Summary Report Print Date: 11/30/2020

Legal Name and Location:

LifeNet Health 5733 Bayside Road Suite 104

Virginia Beach, Virginia 23455

USA

Phone: 757-464-4761 **Ext.:** 4648

Reporting Official:

Michael Plew, SVP,Global Quality&Regulatory Compliance

1864 Concert Drive

Virginia Beach, Virginia 23453

ΙΙςΔ

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)).

	Donor Type(s)	Establishment Functions										
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane					Х	Х	Х	Х				Matrion, AmnioExcite
Blood Vessel					Х	Х	Х	Х	Х			Angiograft
Bone					Х	х	Х	Х	Х			***See full text on next page.
Cardiac Tissue - non-valved					Х	Х	Х	Χ	X			Cardiograft
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia					Х	Х	Х	Χ				
Heart Valve					Х	Х	Х	Χ	Х			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												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Bone	PliaFX Prime, PliaFX Strip, OraGraft, OraGRAFT Prime, OraGRAFT Endure, Salvin Osseofiber, OsseoFiber-PLUS ReadiGraft, ReadiGraft BLX, FlexiGraft, VESUVIUS, Bio DBM,BIO Expand, Straumann Allograft, Salvin Bulk, Neodent Allograft, Straumann Allograft Custom Block
	Bone

FEI: 3005381997 Legal Name: LifeNet Health

Additional Information:

No additional information provided.