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

Ext.:

FEI: 3018120243

Other FDA Registrations: Blood: Devices:

Drugs:

Fatablish mant Freezie

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2025
Last Registration Receipt Date: 11/15/2024
Summary Report Print Date: 12/05/2024

No

Legal Name and Location:

LifeNet Health

2900 Sabre Street, Suite 800

Virginia Beach, Virginia 23452

USA

Phone: 757-264-5500

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:

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)).

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane			х									
Blood Vessel			X									
Bone			Х									
Cardiac Tissue - non-valved			Х									
Cartilage			Х									
Cornea												
Dura Mater												
Embryo												
Fascia			Х									
Heart Valve			Х									
HPC Apheresis												
HPC Cord Blood												
Ligament			Х									
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium			Х									
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			х									
Tendon			х									
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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

The deditional information provides

Proprietary Name(s):

FEI: 3018120243 Legal Name: LifeNet Health