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: 3009672666

Other FDA Registrations: Blood:

Devices:FEI: 3009672666

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025
Last Registration Receipt Date: 11/18/2024
Summary Report Print Date: 12/05/2024

Legal Name and Location:

LifeNet Health Northwest, LLC

Renton, Washington 98057

Phone: 425-981-8900

501 SW 39th Street

USA

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)).

No

	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		Matrion, Biolieve	
Blood Vessel		х			Х	х	Х	Х	Х		AngioGraft	
Bone		х			X	X	Х	Х	Х		***See full text on next page.	
Cardiac Tissue - non-valved		х			X	X	Х	Х	Х		CardioGraft	
Cartilage		х			X	X	Х	Х	Х			FlexiGraft
Cornea												
Dura Mater												
Embryo												
Fascia		X					Х		х			***See full text on next page.
Heart Valve		X			х	x	Х	Х	х			CardioGraft
HPC Apheresis												
HPC Cord Blood												
Ligament		X					Х		х			FlexiGraft
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		X					Х		Х			ReadiGraft
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin		х					Х	<u> </u>	Х		_	***See full text on next page.
Tendon		Х					Х		Х			FlexiGraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional informatio	m. No additional illionnation provided.	
Proprietary Name(s):	Bone	ViviGen, ViviGen Formable, PliaFX Prime, PliaFX Strip, SymALIGN, MatriGraft, ReadiGraft, VertiGraft, FlexiGraft, Optium 100, Fresh Osteochondral Allografts, Osteoarticular Allografts
	Fascia	ReadiGraft, Oragraft. Perio Fascia Lata
	Skin	ReadiGraft, Dermacell, Dermacell AWM, Dermacell Porous, ArthroFLEX, ArthroFLEX BioWasher

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