## 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: 3009672666

Reporting Official:

Other FDA Registrations: Blood:

Devices:FEI: 3009672666

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2020 Last Registration Receipt Date: 11/18/2019 Summary Report Print Date: 12/10/2019

Legal Name and Location:

LifeNet Health Northwest, LLC

Renton, Washington 98057

Phone: 425-981-8900

USA

501 SW 39th Street

Ext.:

Michael Plew, SVP, Global Quality & Regulatory Compliance 1864 Concert Drive

Virginia Beach, Virginia 23453

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)).

					Establishn	nent Function	ons					
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												
Blood Vessel		Х			Х	Х	Х	Х	Х			
Bone		Х			X	Х	Х	Х	Х			
Cardiac Tissue - non-valved		X			X	Х	Х	Х	Х			
Cartilage		X			X	Х	Х	Х	Х			
Cornea												
Dura Mater												
Embryo												
Fascia		Х					Х		Х			
Heart Valve		Х			X	Х	Х	Х	X			
HPC Apheresis												
HPC Cord Blood												
Ligament		Х					Х		Х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		х					Х		х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin		Х					Х		Х			
Tendon		Х					Х		Х			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional	Information:	1

No additional information provided.

Proprietary Name(s):

FEI: 3009672666

Legal Name:

LifeNet Health Northwest, LLC