

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: 1000512996

Other FDA Registrations:
Blood:
Devices:FEI: 1000512996
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
5809 Ward Ct.

Virginia Beach, Virginia 23455
USA

Phone: 757-464-4761

Ext.: 4648

Reporting Official:

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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)).

Establishment Functions

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

Additional Information: No additional information provided.

Proprietary Name(s): Skin	DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX BioWasher, OrACELL, Straumann Allograft
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