

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,          TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS          DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 1000512996	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 1000512996 <b>Drugs:</b>	Reason For Last Submission: Change in Information Last Annual Registration Year: 2020 Last Registration Receipt Date: 12/12/2019 Summary Report Print Date: 01/07/2020
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<b>Legal Name and Location:</b>  LifeNet Health 5809 Ward Ct.   Virginia Beach, Virginia 23455 USA  Phone: 757-464-4761 <b>Ext.:</b> 4648	<b>Reporting Official:</b> Michael Plew, SVP,Global Quality&Regulatory Compliance 1864 Concert Drive Virginia Beach, Virginia 23453 USA Phone: 757-464-4761 Ext. 4648 michael_plew@lifenethealth.org	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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)).
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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										
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.

<b>Proprietary Name(s):</b> Skin	DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX BioWasher, OrACELL, Straumann Allograft
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FEI: 1000512996

Legal Name:

LifeNet Health