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:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2021 Last Registration Receipt Date: 12/10/2020 Summary Report Print Date: 12/14/2020

No

Legal Name and Location:

LifeNet Health 5809 Ward Ct.

Ext.: 4648

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Reporting Official:

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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								1		
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				Х	Х					Matrion, AmnioExcite
Blood Vessel		X										
Bone		Х			Х	Х	Х	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		· · · · · · · · · · · · · · · · · · ·	Х	Х	Х	Х				***See full text on next page.
Tendon		Х										
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Informatio	n: No additional information provided.	
Proprietary Name(s):	Skin	DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX BioWasher, OrACELL, Straumann Allograft
Proprietary Name(s):	Skin	DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX BioWasher, OrACELL, Straumann Allograft

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