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: 2024 Last Registration Receipt Date: 11/17/2023 Summary Report Print Date: 12/01/2023		
Legal Name and Location: LifeNet Health 5809 Ward Ct. Virginia Beach, Virginia 23455 USA Phone: 757-464-4761 Ext.: 4648				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: 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 Functio	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		x			x	х	x	х				Matrion, AmnioExcite, Biolieve	
Blood Vessel		х											
Bone		х			х	х	x	x					
Cardiac Tissue - non-valved		Х											
Cartilage		Х											
Cornea													
Dura Mater													
Embryo													
Fascia		х											
Heart Valve		х											
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		х			х	х	х	х				***See full text on next page.	
Tendon		х											
Testicular Tissue													
Tooth Pulp													
Umbilical Cord Tissue													

Legal Name:

Additional Information: No additional information provided.

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

FEI: 1000512996

Legal Name:

LifeNet Health