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

Ext.:

FEI: 3015724777

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2020
Last Registration Receipt Date: 11/18/2019

No

Legal Name and Location:

LifeNet Health 845 Airtech Parkway Suite 198

Plainfield, Indiana 46168 USA

Phone: 317-754-3000

Reporting Official:

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

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Summary Report Print Date: 12/10/2019

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)).

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

Additional Information	on: No additional information provided.	
Proprietary Name(s):	Bone	ViviGen, ViviGen Formable, PliaFX Prime, PliaFX Strip, SymALIGN, MatriGraft, OraGraft, ReadiGraft ,VertiGraft AlloOss, VIKOS, Straumann Allograft Ring, Straumann Custom Block, Straumann Allograft, BIO AVS, Trinnect, BIO Chips, BIO Wedge, BIO Shaft, MatriSPINE, FlexiGraft, ReadiGraft BLX, OraGraft, OraGRAFT Prime, OraGRAFT Endure, OsseoFiber, OsseoFiber-PLUS
	Skin	ReadiGraft, DermACELL, DermACELL AWM, OrACELL, ArthroFLEX, ArthroFLEX BioWasher, TheraSkin, Straumann Allograft

FEI: 3015724777 Legal Name: LifeNet Health