## 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: 3015356376

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

No

Legal Name and Location:

LifeNet Health

4224 Campus Point Court #120

San Diego, California 92121

USA

Phone: 757-464-4761 **Ext.:** 

Reporting Official:

Michael Plew, SVP, Global Quality&Regulatory Compliance

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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)).

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

Additional Information	n: No additional information provided.	
Proprietary Name(s):	Bone	ViviGen, ViviGen Formable, PliaFX Prime, PliaFX Strip, Optium100, OraGEN
	Skin	ReadiGraft, TheraSkin, DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX Biowasher

FEI: 3015356376 Legal Name: LifeNet Health