

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: 2020  
Last Registration Receipt Date: 11/18/2019  
Summary Report Print Date: 12/10/2019

**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  
1864 Concert Drive  
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)).

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												
Bone								X		X		***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								X		X		***See full text on next page.
Tendon								X		X		FlexiGraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** No additional information provided.

<b>Proprietary Name(s):</b>	Bone	ViviGen, ViviGen Formable, PliaFX Prime, PliaFX Strip
	Skin	ReadiGraft, TheraSkin, DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX Biowasher

FEI: 3015356376

Legal Name:

LifeNet Health