

FEI: 3015724777

Other FDA Registrations:
Blood:
Devices:
Drugs:

Reason For Last Submission: Initial Registration/Listing
 Last Annual Registration Year: 2019
 Last Registration Receipt Date: 11/04/2019
 Summary Report Print Date: 11/04/2019

Legal Name and Location:

LifeNet Health
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Plainfield, Indiana 46168
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Reporting Official:

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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)).

Establishment Functions

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	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage							X	X	X			Flexigraft
Cornea												
Dura Mater												
Embryo												
Fascia							X	X	X			ReadiGraft, OraGraft
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							X	X	X			FlexiGraft
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium							X	X	X			ReadiGraft
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin							X	X	X			***See full text on next page.
Tendon							X	X	X			FlexiGraft
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Bone proprietary names (cont): Straumann Allograft Ring, BIO AVS, Trinnect, BIO Chips, BIO Wedge, BIO Shaft, MatriSPINE, FlexiGraft, Readigraft BLX

Proprietary Name(s): Bone	ViviGen, ViviGen Formable, PliaFX Prime, PliaFX Strip, SymALIGN, MatriGraft, OraGraft, Readigraft, VertiGraft AlloOss, VIKOS
Skin	Readigraft, DermACELL, DermACELL AWM, OrACELL, ArthroFLEX, ArthroFLEX BioWasher, TheraSkin

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