

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,          TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS          DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3015724777	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 3015724777 <b>Drugs:</b>	Reason For Last Submission: Change in Information Last Annual Registration Year: 2020 Last Registration Receipt Date: 12/12/2019 Summary Report Print Date: 01/07/2020
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<b>Legal Name and Location:</b>  LifeNet Health 845 Airtech Parkway Suite 198  Plainfield, Indiana 46168 USA  Phone: 317-754-3000 <b>Ext.:</b>	<b>Reporting Official:</b>  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	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> 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)).
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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:** No additional information provided.

<b>Proprietary Name(s):</b>	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

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Legal Name:

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