| 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: 2021 Last Registration Receipt Date: 11/17/2020 Summary Report Print Date: 11/30/2020 | | |
|---|---------------|---------|-------------------------|---|---------|---------|--|-------|------------|---|---|--------------------------------|--|
| 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.: 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) | 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 | | | ***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 | | | | | | | | | | | | | |

Legal Name:

Additional Information: No additional information provided.

| Proprietary Name(s): | Bone | ViviGen, ViviGen Formable, PliaFX Prime, PliaFX Strip |
|----------------------|------|---|
| | | |
| | Skin | ReadiGraft, TheraSkin, DermACELL, DermACELL AWM, ArthroFLEX, ArthroFLEX Biowasher |
| | | |

FEI: 3015356376

Legal Name:

LifeNet Health