| 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: 1000525281 | | | Blood Devic | Other FDA Registrations: Blood: FEI: 1000525281 Devices: Drugs: | | | | Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/16/2023 Summary Report Print Date: 12/01/2023 | | |
|---|----------------------------|---------|---|---------------|-------------------------|----------------|--|-------|------------|---------------------------|--|---------------------|--|
| Legal Name and Location: Cord For Life 270 Northlake Boulevard, Suite 1012 Altamonte Springs, Florida 32701 USA Phone: 407-834-8333 Ext.: | | | Reporting Official: Deborah A Sardone, QA Manager 270 Northlake Boulevard Suite 1012 Altamonte Springs, Florida 32701 USA Phone: 407-834-8333 Ext. dsardone@cordforlife.com | | | | | | | | 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 12716)). | | |
| | | | 1 | | 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 | | | | | | | | | | | | | |
| Cardiac Tissue - non-valved | | | | | | | | | | | | | |
| Cartilage | | | | | | | | | | | | | |
| Cornea | | | | | | | | | | | | | |
| Dura Mater | | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | | |
| Fascia | | | | | | | | | | | | | |
| Heart Valve | | | | | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | | |
| HPC Cord Blood | Autologous, Family Related | x | х | х | х | х | х | х | x | | | | |
| Ligament | | | | | | | | | | | | | |
| Nerve Tissue | | | | | | | | | | | | | |
| Oocyte | | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | | |
| Pericardium | | | | | | | | | | | | | |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | | |
| Sclera | | | | | | | | | | | | | |
| Semen | | | | | | | | | | 22-OCT-23 | | | |
| Skin | | | | | | | | | | | | | |
| Tendon | | | | | | | | | | | | | |
| Testicular Tissue | | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | | |
| Umbilical Cord Tissue | | x | x | х | х | Х | x | х | x | | | | |

Legal Name:

Additional Information: HPC, Cord Blood Autologous, Family Related and Allogenic

Proprietary Name(s):

FEI: 1000525281

Legal Name:

Cord For Life