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| 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: 3003415347 | Other FDA Registrations: Blood: Devices: FEI: 3003415347 Drugs: | Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2021 Last Registration Receipt Date: 12/08/2020 Summary Report Print Date: 12/14/2020 |
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| Legal Name and Location: TissueTech, Inc. 7000 SW 97th Avenue Suite 118 Miami, Florida 33173 USA Phone: 786-637-6561 Ext.: | Reporting Official: Lorraine Chua, Director of Regulatory Affairs 7300 Corporate Center Drive Suite 700 Miami, Florida 33126 USA Phone: 786-456-7719 Ext. lchua@tissuetechinc.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 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 | | | | | X | X | X | X | X | | | ***See full text on next page. |
| Blood Vessel | | | | | | | | | | | | |
| Bone | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | |
| Tendon | | | | | | | | | | | | |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | X | X | X | X | X | | | ***See full text on next page. |

Additional Information:

Historical Listing:

Amniotic Membrane: AmnioGraft, AmnioGraft ST, CLARIX 100, CLARIX 100 RT, CLARIX FLO, NEOX 100, NEOX 100 RT, NEOX 100 ST, NEOX FLO, PROKERA, PROKERA Slim, PROKERA Plus, PROKERA Clear

Umbilical Cord: AmnioGuard, AmnioGuard ST, CLARIX CORD, CLARIX CORD 1K, CLARIX CORD RT, CLARIX GEL, NEOX CORD, NEOX CORD 1K, NEOX CORD RT, NEOX GEL, RESPINA, RESPINA CORD 1K, BTGEL, rBTGEL, Regenesol

Placenta: AXFILL

Proprietary Name(s):

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| Amniotic Membrane | AmnioGraft, AmnioGraft ST, CLARIX 100, CLARIX FLO, NEOX 100, NEOX FLO, PROKERA, PROKERA Clear, PROKERA Plus, PROKERA Slim |
| Umbilical Cord Tissue | AmnioGuard, CLARIX CORD 1K, CLARIX FLO, NEOX CORD 1K, NEOX CORD RT, NEOX FLO, RESPINA, RESPINA CORD 1K |

FEI: 3003415347

Legal Name:

TissueTech, Inc.