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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,<br/>         TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS<br/>         DESCRIBED IN 21 CFR 1271.10</b> | <b>FEI:</b> 3006717666 | <b>Other FDA Registrations:</b><br><b>Blood:</b><br><b>Devices:</b> FEI: 3003415347<br><b>Drugs:</b> | Reason For Last Submission: Change in Information<br>Last Annual Registration Year: 2019<br>Last Registration Receipt Date: 05/10/2019<br>Summary Report Print Date: 07/18/2019 |
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| <b>Legal Name and Location:</b><br><br>TissueTech, Inc.<br>11315 Rancho Bernardo Road<br>Suite 140/141<br><br>San Diego, California 92127<br>USA<br>Phone: 786-637-6561 | <b>Reporting Official:</b><br><br>Lorraine Chua, Director of Regulatory Affairs<br>7300 Corporate Center Drive<br>Suite 700<br>Miami, Florida 33126<br>USA<br>Phone: 786-456-7719 Ext.<br>lchua@tissuetechinc.com | <b>Satellite Recovery Establishment:</b> No<br><b>Parent Manufacturing Establishment FEI No.:</b><br><b>Testing For Micro-Organisms Only:</b> No<br><br>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          |                        |                    | ***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          |                        |                    | ***See full text on next page. |

**Additional Information:**

Historical Listing:

Amniotic Membrane: Neox 100, Clarix 100, Neox Flo, Clarix Flo, Prokera Slim, Prokera Plus, Prokera Clear, Prokera, AmnioGraft, Neox 100 RT, Clarix 100 RT, AmnioGraft ST  
Umbilical Cord: AmnioGuard, Neox Cord 1K, Clarix Cord 1K, Neox Cord, Clarix Cord, AmnioGuard ST, Neox Cord RT, Clarix Cord RT, Neox GEL, Clarix GEL, Respina, BTGEL, rBTGEL, Regenesol  
Placenta: AXFILL

**Proprietary Name(s):**

Amniotic Membrane Neox100, Clarix100, Neox Flo, Clarix Flo, Prokera Slim, Prokera Plus, Prokera Clear, Prokera, AmnioGraft  
Umbilical Cord AmnioGuard, Neox Cord 1k, Clarix Cord 1k, Neox Cord, Clarix Cord  
Tissue