

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> 3003415347	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> FEI: 3003415347 <b>Drugs:</b>	Reason For Last Submission: Change in Information Last Annual Registration Year: 2019 Last Registration Receipt Date: 05/15/2019 Summary Report Print Date: 07/18/2019
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<b>Legal Name and Location:</b>  TissueTech, Inc. 7000 SW 97th Avenue Suite 118  Miami, Florida 33173 USA Phone: 786-637-6561	<b>Reporting Official:</b> Lorraine Chua, Director of Regulatory Affairs 7300 Corporate Center Drive Suite 700 Miami, Florida 33126 USA Phone: 786-456-7719 Ext. lchua@tissuetechinc.com	<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					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: 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