

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: 3009809074	Other FDA Registrations: Blood: Devices: FEI: 3003415347 Drugs:	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
--	------------------------	--	---

Legal Name and Location: TissueTech, Inc. 8305 NW 27th Street, Suite 101 Doral, Florida 33122 USA Phone: 786-637-6561	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)).
---	---	--

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	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	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