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 (HCT/Ps)

(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3006717666

2. REASON FOR SUBMISSION

a. ☐ INITIAL REGISTRATION / LISTING
b. ☒ ANNUAL REGISTRATION / LISTING
c. ☐ CHANGE IN INFORMATION
d. ☐ INACTIVE

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:28-DEC-2017
DISTRICT: Los Angeles
PRINTED BY FDA:27-JAN-2018

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____

b. DEVICES FDA 2891 NO. FEI: 3003415347

c. DRUG FDA 2656 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)

TissueTech, Inc.

11315 Rancho Bernardo Road
Suite 140/141
San Diego, California 92127

a. PHONE (786) 517-6288 EXT

b. ☐ SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO._____

c. ☐ TESTING FOR MICRO-ORGANISMS ONLY

5. ENTER CORRECTIONS TO ITEM 4

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

TissueTech, Inc.
Attn: Joseph A. Jimenez
8305 NW 27th Street
Suite 101
Doral, Florida 33122

a. PHONE 786-517-6288 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Joseph A. Jimenez

b. E-MAIL jjimenez@tissuetechinc.com

c. TITLE VP, Quality and Regulatory Affairs d. DATE 28-DEC-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

Types of HCT / Ps	Establishment Functions: Recover	Screen	Test	Package	Process	Store	Label	Distribute	11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo ☐ SIP ☐ Directed ☐ Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte ☐ SIP ☐ Directed ☐ Anonymous												
j. Pericardium												
k. Peripheral Blood Stem ☐ Autologous ☐ Family Related ☐ Allogeneic												
l. Sclera												
m. Semen ☐ SIP ☐ Directed ☐ Anonymous												
n. Skin												
o. Somatic Cell Therapy Products ☐ Autologous ☐ Family Related ☐ Allogeneic												
p. Tendon												
q. Umbilical Cord Blood ☐ Autologous ☐ Family Related ☐ Allogeneic												
r. Vascular Graft												
s. Amniotic Membrane				X		X	X	X	X	X		*** See full text on next page
t. Umbilical Cord				X		X	X	X	X			*** See full text on next page
u.												
v.												

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ADDITIONAL INFORMATION:

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