

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: 3012088418

2. REASON FOR SUBMISSION
a. INITIAL REGISTRATION / LISTING
b. ANNUAL REGISTRATION / LISTING
c. CHANGE IN INFORMATION
d. INACTIVE

VALIDATION--FOR FDA USE ONLY
VALIDATED BY FDA: 15-DEC-2017
DISTRICT: Dallas
PRINTED BY FDA: 27-JAN-2018

See Instructions for OMB Statement FORM APPROVED OMB No. 0910-00543, Expiration Date: 6/30/2020

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2890 NO. FEI: 0001671794
b. DEVICES FDA 2891 NO. _____
c. DRUG FDA 2856 NO. _____

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
United Tissue Resources, LLC
591 Spencer Lane
San Antonio, Texas 78201

5. ENTER CORRECTIONS TO ITEM 4
a. PHONE 210-733-8485 EXT _____
b. SATELLITE RECOVERY ESTABLISHMENT
(MANUFACTURING ESTABLISHMENT FEI NO. _____)
c. TESTING FOR MICRO-ORGANISMS ONLY

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)
United Tissue Resources, LLC
Attn: Wendy Bailey
591 Spencer Lane
San Antonio, Texas 78201

7. ENTER CORRECTIONS TO ITEM 6
a. PHONE 512-206-1134 EXT _____
b. PHONE _____

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE
Wendy Bailey 01-30-18
a. TYPED NAME Wendy Bailey
b. E-MAIL wbailey@ctcms.com
c. TITLE Director, Quality Assurance
d. DATE 15-DEC-2017

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS	Establishment Functions						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)
	Recover	Screen	Test	Package	Process	Store				
a. Bone						X			X	
b. Cartilage						X			X	
c. Cornea										
d. Dura Mater										
e. Embryo										
f. Fascia										
g. Heart Valve										
h. Ligament						X			X	
i. Oocyte										
j. Pericardium										
k. Peripheral Blood Stem										
l. Sclera										
m. Semen										
n. Skin						X			X	
o. Somatic Cell Therapy Products						X			X	
p. Tendon						X			X	
q. Umbilical Cord Blood										
r. Vascular Graft										
s. Amniotic Membrane						X			X	
t. Nerve Tissue						X			X	
u.										
v.										