

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: 3001238005

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

VALIDATION--FOR FDA USE ONLY
DISTRICT: Dallas
PRINTED BY FDA: 27-JAN-2018

14. PROPRIETARY NAME(S)

13. HCT/PS REGULATED AS DRUGS OR BIOLOGICAL DRUGS

12. HCT/PS REGULATED AS MEDICAL DEVICES

11. HCT/PS DESCRIBED IN 21 CFR 1271.10

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / PS	Establishment Functions							14. PROPRIETARY NAME(S)
	Recover	Screen	Test	Package	Process	Store	Distribute	
a. Bone	X	X		X		X	X	
b. Cartilage	X	X		X	X	X	X	
c. Cornea	X	X		X	X	X	X	
d. Dura Mater								
e. Embryo								
f. Fascia	X	X		X	X	X	X	
g. Heart Valve	X	X					X	
h. Ligament	X	X				X	X	
i. Oocyte								
j. Pericardium	X	X				X	X	
k. Peripheral Blood Stem								
l. Sclera	X	X		X	X	X	X	
m. Semen								
n. Skin	X	X		X	X	X	X	
o. Somatic Cell Therapy Products								
p. Tendon	X	X				X	X	
q. Umbilical Cord Blood								
r. Vascular Graft	X	X					X	
s. Amniotic Membrane						X	X	Prokera
t. Nerve Tissue						X	X	Avance
u.								
v.								

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO.
b. DEVICES FDA 2891 NO.
c. DRUG FDA 2656 NO.

4. PHYSICAL LOCATION (include legal name, number and street, city, state, country, and post office code)
Transplant Services Center UT Southwestern Medical Center
5323 Harry Hines, MC 9074
Dallas, Texas 75390-9074

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)
Transplant Services Center, UT Southwestern Medical Center
Attn: Kiara M. Cotton, MHA, RN, BSN, CTBS
5323 Harry Hines, MC 9074
Dallas, Texas 75390-9074

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

9. REPORTING OFFICIAL'S SIGNATURE
K Cotton

a. TYPED NAME Kiara M. Cotton, MHA, RN, BSN, CTBS
b. E-MAIL kiara.cotton@utsouthwestern.edu
c. TITLE QA Coordinator
d. DATE 16-NOV-2017