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)

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
   a. BLOOD FDA 2830 NO.
   b. DEVICES FDA 2891 NO.
   c. DRUG FDA 2668 NO.

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
   Transplant Services Center UT Southwestern Medical Center
   5232 Harry Hines, MC 9074
   Dallas, Texas 75390-9074

   a. PHONE 214-648-2609 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)
   Transplant Services Center, UT Southwestern Medical Center
   Attn: Kiara M. Cotton, MHA, RN, BSN, CTBS
   5232 Harry Hines, MC 9074
   Dallas, Texas 75390-9074

   a. PHONE 214-648-8402 EXT
   b. PHONE

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

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

   a. Bone X X
   b. Cartilage X X X X X X X X
   c. Cornea X X X X X X X X
   d. Dura Mater X
   e. Embryo SIP Directed Anonymous
   f. Fascia X X X X X X X
   g. Heart Valve X X
   h. Ligament X X
   i. Oocyte SIP Directed Anonymous
   j. Pericardium X X X X X
   k. Peripheral Blood Stem Autologous Family Related Allogeneic
   l. Sclera X X X X X X
   m. Semen SIP Directed Anonymous
   n. Skin X X X X X X X
   o. Somatic Cell Therapy Products Autologous Family Related Allogeneic
   p. Tendon X X X
   q. Umbilical Cord Blood Autologous Family Related Allogeneic
   r. Vascular Graft X X
   s. Amniotic Membrane X X X X Prokera
   t. Nerve Tissue X X X Avance
   u.
   v.

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