See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

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: 0001071757

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

VALIDATION--FOR FDA USE ONLY 1
VALIDATED BY FDA:29-DEC-2016
DISTRICT: Atlanta
PRINTED BY FDA:09-JAN-2017

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 0001071757
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)
Medical University Hospital Authority

Laboratory Services-Transfusion Medicine
165 Ashley Avenue
MSC 908
Charleston, South Carolina 29425

a. PHONE 843-792-2671 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)
Medical University Hospital Authority
Attn: Karen S. Garner, MHA, MT(ASCP)SBB
Laboratory Services-Transfusion Medicine
165 Ashley Avenue
MSC 908
Charleston, South Carolina 29425

a. PHONE 843-792-2671 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Karen S. Garner, MHA, MT(ASCP)SBB
b. E-MAIL garnerk@musc.edu
c. TITLE Transfusion Medicine Manager d. DATE 28-DEC-2016

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 [X] Autologous [X] Family Related [X] Allogeneic	X	X		X	X	X	X	X	X		X	
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 [X] Family Related [X] Allogeneic						X					X	
r. Vascular Graft												
s. Therapeutic Cells	X	X		X	X	X	X	X	X		X	
t.												
u.												
v.												