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

COPY

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: 3001779663

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:20-NOV-2015
DISTRICT: Dallas
PRINTED BY FDA:03-DEC-2015

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)

Arkansas Regional Organ Recovery Agency

1701 Aldersgate Road, Suite 4
Little Rock, Arkansas 72205

a. PHONE 501-907-9131 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)

Arkansas Regional Organ Recovery Agency
Attn: Patricia A. Gottschall
1701 Aldersgate Road, Suite 4
Little Rock, Arkansas 72205

a. PHONE 501-749-5731 EXT
b. PHONE

7. ENTER CORRECTIONS TO ITEM 6

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

Patricia A. Gottschall 12-4-15

a. TYPED NAME Patricia A. Gottschall
b. E-MAIL pgottschall@arora.org
c. TITLE Director of Quality Systems
d. DATE 19-NOV-2015

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

FORM FDA - 3356 (5/14)