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 (Field Establishment Identifier)
FEI: 3000204058

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

VALIDATION–FOR FDA USE ONLY 1
VALIDATED BY FDA:02-JAN-2008
DISTRICT: Los Angeles
PRINTED BY FDA:17-JAN-2008

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS
a. BLOOD FDA 2830 NO. FEI: 0002077975
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)*
Blood Systems, Inc.
Blood Systems Laboratories
2424 West Erie Drive
Tempe, Arizona 85252

a. PHONE 602-343-7000 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)*
Blood Systems, Inc.
Attn: Mary Beth Bassett
~~6210 East Oak St.~~
Scottsdale, Arizona 85257

a. PHONE 480-946-4201 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

a. TYPED NAME Mary Beth Bassett
b. E-MAIL mbassett@bloodsystems.org
c. TITLE VP QM / RA d. DATE 31-DEC-2007

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)
No HCT / P Specified												
a. Bone			X						X			
b. Cartilage			X						X			
c. Cornea			X						X			
d. Dura Mater			X						X			
e. Embryo ☐ SIP ☐ Directed ☒ Anonymous			X						X			
f. Fascia			X						X			
g. Heart Valve			X						X			
h. Ligament			X						X			
i. Oocyte ☐ SIP ☐ Directed ☒ Anonymous			X						X			
j. Pericardium			X						X			
k. Peripheral Blood Stem Cells ☒ Autologous ☒ Family Related ☒ Allogeneic			X						X		X	
l. Sclera			X	X	X	X	X	X	X			
m. Semen ☐ SIP ☐ Directed ☒ Anonymous			X						X			
n. Skin			X						X			
o. Somatic Cells ☒ Autologous ☒ Family Related ☒ Allogeneic			X						X			
p. Tendon			X						X			
q. Umbilical Cord Blood Stem Cells ☐ Autologous ☐ Family Related ☒ Allogeneic			X		X	X	X	X	X		X	
r. Vascular Graft			X						X			
s. Bone Marrow Derived Stem Cells			X	X	X	X	X	X	X			
t.												
u.												
v.												