See Instructions for OMB Statement FORM APPROVED: OMB No. 0910-0543. Expiration Date: 1/31/14

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: 0002275064

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:13-JAN-2012
DISTRICT: New Jersey
PRINTED BY FDA:17-JAN-2012

PART I - ESTABLISHMENT INFORMATION

3. OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. FEI: 0002275064
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)*

Bergen Community Regional Blood Center dba Community Blood Services
970 Linwood Avenue West
Paramus, New Jersey 07652

a. PHONE 201-444-3900 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)*

Bergen Community Regional Blood Center dba Community Blood Services
Attn: Kathleen McKenna, CQIA (ASQ)
970 Linwood Avenue West
Paramus, New Jersey 07652

a. PHONE 201-251-3721 EXT

7. ENTER CORRECTIONS TO ITEM 6 b. PHONE

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

Kathleen McKenna

a. TYPED NAME Kathleen McKenna, CQIA (ASQ)
b. E-MAIL KathleenMc@cbsblood.org
c. TITLE AVP QA/RA d. DATE 27-DEC-2011

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 Cells ☒ Autologous ☒ Family Related ☒ 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 Stem Cells ☒ Autologous ☒ Family Related ☒ Allogeneic			X						X		X	
r. Vascular Graft												
s.												
t.												
u.												
v.												

FORM FDA 3356 (4/08)