

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: 3006399760

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:02-JAN-2009
DISTRICT: New Jersey
PRINTED BY FDA:05-JAN-2009

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)*

Bergen Community Regional Blood Center dba Elie Katz Umbilical Cord Blood dba NJCBB
1 Pearl Court
Allendale, New Jersey 07401

a. PHONE 201-444-3900 EXT 1902
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 Elie Katz Umbilical Cord Blood dba NJCBB
Attn: Dennis M. Todd, Ph.D.
970 Linwood Avenue West
Paramus, New Jersey 07653

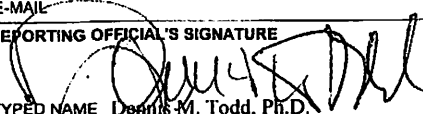
a. PHONE 201-251-3702 EXT _____

7. ENTER CORRECTIONS TO ITEM 6

b. PHONE _____

8. U.S. AGENT

a. E-MAIL
9. REPORTING OFFICIAL'S SIGNATURE



a. TYPED NAME Dennis M. Todd, Ph.D.
b. E-MAIL DennisT@CBSBLOOD.ORG
c. TITLE CEO

d. DATE 15-DEC-2008

PART II - PRODUCT INFORMATION

Types of HCT / Ps	Establishment Functions								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)
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
a. Bone												
b. Cartilage												
c. Cornea												
d. Dura Mater												
e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
f. Fascia												
g. Heart Valve												
h. Ligament												
i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
j. Pericardium												
k. Peripheral Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic					X				X	X		
l. Sclera												
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
n. Skin												
o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
p. Tendon												
q. Umbilical Cord Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X	X	X	X	X	X	X	X		X	
r. Vascular Graft												
s.												
t.												
u.												
v.												