

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: 3004521286

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

OTHER FDA REGISTRATIONS

a. BLOOD FDA 2830 NO. _____
b. DEVICES FDA 2891 NO. _____
c. DRUG FDA 2656 NO. _____

PHYSICAL LOCATION *(Include legal name, number and street, city, state, country, and post office code)*

HLA Registry
800 Kinderkamack Road
Suite 300
Oradell, New Jersey 07649

PHONE 2017051615 EXT _____

SATELLITE RECOVERY ESTABLISHMENT
 MANUFACTURING ESTABLISHMENT FEI NO. _____
 TESTING FOR MICRO-ORGANISMS ONLY

ENTER CORRECTIONS TO ITEM 4

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
Attn: Dennis M. Todd, PhD
970 Linwood Avenue West
Paramus, New Jersey 07652

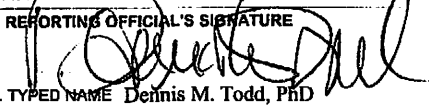
PHONE 201-251-3702 EXT _____

ENTER CORRECTIONS TO ITEM 6 b. PHONE _____

U.S. AGENT

i. E-MAIL

REPORTING OFFICIAL'S SIGNATURE



TYPED NAME Dennis M. Todd, PhD

i. E-MAIL DENNIST@CBSBLOOD.ORG

ii. TITLE CEO/President

d. DATE 12-DEC-2008

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / PS

Types of HCT / Ps	Establishment Functions									11. HCT/PS DESIGNED 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 checked="" 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 type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic													
r. Vascular Graft													
s.													
t.													
u.													
v.													