

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: 0002970033

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:30-DEC-2008
 DISTRICT: San Francisco
 PRINTED BY FDA:05-JAN-2009

PART I - ESTABLISHMENT INFORMATION

OTHER FDA REGISTRATIONS
 a. BLOOD FDA 2830 NO. FEI: 0002970033
 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)
 UCSF Medical Center Clinical Lab, HPCT Lab
 505 Parnassus Avenue, Room M547
 San Francisco, California 94143-0100

PHONE 415-353-1789 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)
 UCSF Medical Center Clinical Laboratory
 Attn: Pearl Toy, MD
 505 Parnassus Avenue, Room M501
 Box 0100
 San Francisco, California 94143-0100

PHONE 415-353-1671 EXT _____
ENTER CORRECTIONS TO ITEM 6 b. PHONE _____

U.S. AGENT

E-MAIL _____
REPORTING OFFICIAL'S SIGNATURE

TYPED NAME Pearl Toy, MD
 E-MAIL pearl.toy@clinlab.ucsfmedctr.org
 TITLE Medical Director Blood Bank d. DATE 19-DEC-2008

PART II - PRODUCT INFORMATION

10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps

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 checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X	X	X	X	X	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 checked="" type="checkbox"/> Allogeneic			X	X	X	X	X	X	X			X	
r. Vascular Graft													
s.													
t.													
u.													
v.													