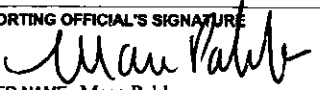


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3001503330	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION—FOR FDA USE ONLY *3001503330* VALIDATED By FDA: 12/03/07 PRINTED By FDA: 12/07/07 DISTRICT: Los Angeles
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION										11. HCT/Ps DESCRIBED IN 21 CFR 127.1.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps													
	Establishment Functions													
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute					
	No HCT / P Specified													
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> California Transplant Services, Inc. 5845 Owens Avenue Carlsbad, California 92008 a. PHONE 760-804-6890 EXT 101 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X				X	X	X	X			VertiGraft	
	b. Cartilage	X	X				X		X	X				
	c. Cornea	X	X		X	X	X	X	X	X				
	d. Dura Mater													
	e. Embryo													
		<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	f. Fascia	X	X				X		X	X				
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve	X	X				X		X	X			CardioGRAFT	
	h. Ligament	X	X				X		X	X				
	i. Oocyte													
		<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
	j. Pericardium													
6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> California Transplant Services, Inc. Attn: Marc Pablo P.O. Box 130815 Carlsbad, California 92013-0815 a. PHONE 760-804-6890 EXT 101	k. Peripheral Blood Stem Cells													
		<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	l. Sclera						X		X	X				
	m. Semen													
		<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
7. ENTER CORRECTIONS TO ITEM 6	n. Skin	X	X				X		X	X				
	o. Somatic Cells													
		<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
8. U.S. AGENT	p. Tendon	X	X				X		X	X				
	q. Umbilical Cord Blood Stem Cells													
		<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
a. E-MAIL	r. Vascular Graft	X	X				X		X	X				
9. REPORTING OFFICIAL'S SIGNATURE 	s.													
a. TYPED NAME Marc Pablo b. E-MAIL mpablo@catransplant.org c. TITLE Vice President	t.													
d. DATE 21-NOV-2007	u.													
	v.													

1. REGISTRATION NUMBER
(Field Establishment Identifier)

FEI: 3001503330

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PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/TPs)**
(See reverse side for instructions)

ADDITIONAL INFORMATION:

Bone-Label=Autologous Donor

Proprietary Name(s):