

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS)</b> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3001503330	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> 1 VALIDATED BY FDA:29-DEC-2010 DISTRICT: Los Angeles PRINTED BY FDA:05-JAN-2011
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION									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)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps												
	<i>Establishment Functions</i>												
	<i>Types of HCT / Ps</i>												
	Recover	Screen	Test	Package	Process	Store	Label	Distribute					
a. BLOOD FDA 2830 NO. _____  b. DEVICES FDA 2891 NO. _____  c. DRUG FDA 2656 NO. _____													
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> California Transplant Services, Inc. dba SafetyGraft 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				*** See full text on next pag
	b. Cartilage					X		X	X				
	c. Cornea					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				
<b>5. ENTER CORRECTIONS TO ITEM 4</b>	g. Heart Valve												
	h. Ligament					X		X	X				
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous												
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> California Transplant Services, Inc. dba SafetyGraft Attn: Marc Pablo, CEBT, CTBS 5845 Owens Ave. Carlsbad, California 92008  a. PHONE 760-804-6890 EXT 101	j. Pericardium												
	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												
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE	n. Skin					X		X	X				Donor and Autologous Skin
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
<b>8. U.S. AGENT</b>  a. E-MAIL	p. Tendon					X		X	X				
	q. Umbilical Cord Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
	r. Vascular Graft												
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Marc Pablo, CEBT, CTBS b. E-MAIL mpablo@catransplant.org c. TITLE Sr. Vice President d. DATE 21-DEC-2010	s. Amniotic Membrane					X		X	X				
	t. Parathyroid					X		X	X				Autologous Parathyroid
	u.												
	v.												

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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)*

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(Field Establishment Identifier)

2

FEI: 3001503330

**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

a. Bone            Autologous Bone, Donor Bone, SpinalGraft MDII,  
                         Precision Graft