

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 (FDA 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 VALIDATED BY FDA:04-DEC-2017 DISTRICT: Los Angeles PRINTED BY FDA:27-JAN-2018
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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											
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	Establishment Functions											
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 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		Autologous Bone
	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		
	g. Heart Valve											
	h. Ligament						X		X	X		
	i. Oocyte											
	<input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	j. Pericardium											
	k. Peripheral Blood Stem											
	<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											
5. ENTER CORRECTIONS TO ITEM 4	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											
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) California Transplant Services, Inc. dba SafetyGraft Attn: Marc Pablo, CEBT, CTBS 5845 Owens Avenue Carlsbad, California 92008 a. PHONE 760-804-6890 EXT 101	p. Tendon						X		X	X		
	q. Umbilical Cord Blood											
	<input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
7. ENTER CORRECTIONS TO ITEM 6	r. Vascular Graft											
	s. Parathyroid						X		X	X		Autologous Parathyroid
	t.											
	u.											
	v.											
8. U.S. AGENT a. E-MAIL												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Marc Pablo, CEBT, CTBS b. E-MAIL mpablo@catransplant.org c. TITLE Sr. Vice President												
	d. DATE 04-DEC-2017											