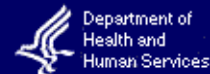




# U.S. Food and Drug Administration



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### eHCTERS - Registration Information

#### Submitted Registration Information

This information has been submitted to the FDA  
Please Remember Your Confirmation Number to Reference this FORM FDA - 3356 Submission  
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Please print this document and maintain as confirmation of your submission.  
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FEI: 3001503330

#### Other FDA Registrations

- Blood FDA 2830  
 Devices FDA 2891  
 Drug FDA 2656

#### Reason for Submission

- Initial Registration/Listing  
 Annual Registration/Listing  
 Change in Information  
 In-Activate Registration

#### Physical Location

Legal Name: California Transplant Services, Inc. dba SafetyGraft  
Street Address: 5845 Owens Avenue  
City: Carlsbad  
State: California  
Postal Code: 92008  
Country: United States  
Phone: 760-804-6890 ext.101

#### Reporting Official Information

First Name: Marc  
Last Name: Pablo CEBT, CTBS  
Title: Sr. Vice President  
Phone: 760-804-6890 Ext.101  
E-Mail Address: mpablo@catransplant.org

#### Mailing Address of Reporting Official

Institution Name: California Transplant Services, Inc. dba SafetyGraft  
Street Address: 5845 Owens Ave.  
City: Carlsbad  
State: California  
Postal Code: 92008  
Country: United States

#### HCT/P Listing Information

	Types of HCT/P's	HCT/P's Described in 21 CFR 1271.10	HCT/P's Regulated as Medical Devices	HCT/P's Regulated as Drugs or Biological Drugs	Proprietary Names
a.	Bone	X			SpinalGraft MDII, Precision Graft

b.	Cartilage	X			
c.	Cornea	X			
d.	Dura Mater				
e.	Embryo				
f.	Fascia	X			
g.	Heart Valve	D			
h.	Ligament	X			
i.	Oocyte				
j.	Pericardium				
k.	Peripheral Blood Stem Cells				
l.	Sclera	X			
m.	Semen				
n.	Skin	X			
o.	Somatic Cell Therapy Products				
p.	Tendon	X			
q.	Umbilical Cord Blood Stem Cells				
r.	Vascular Graft	D			
s.	Amniotic Membrane	X			
t.	Parathyroid	X			

**HCT/P Listing - Function Information**

	Types of HCT/P's	Recover	Screen	Test	Package	Process	Store	Label	Distribute
a.	Bone						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
b.	Cartilage						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
c.	Cornea						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
d.	Dura Mater								
e.	Embryo								
f.	Fascia						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
g.	Heart Valve								
h.	Ligament						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
i.	Oocyte								
j.	Pericardium								
k.	Peripheral Blood Stem Cells								
l.	Sclera						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
m.	Semen								
n.	Skin						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
o.	Somatic Cell Therapy Products								
p.	Tendon						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
q.	Umbilical Cord Blood Stem Cells								
r.	Vascular Graft								
s.	Amniotic Membrane						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
t.	Parathyroid						<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>

**HCT/P Listing - Donor Information**

	Types of HCT/P's	SIP	Directed	Anonymous	Autologous	Family Related	Allogeneic
e.	Embryo						
i.	Oocyte						
k.	Peripheral Blood Stem Cells						
m.	Semen						
o.	Somatic Cell Therapy Products						
q.	Umbilical Cord Blood Stem Cells						

Select New Establishment

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DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION  
ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  
TISSUES AND CELLULAR AND TISSUE-BASED PRODUCTS (eHCTERS)

Electronic Form version 2.2.0  
Updated 11/15/2007

FORM FDA - 3356(4/08) Form Approved:OMB No.0910-0543  
Expiration Date: August 31, 2010

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