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 DESCRIBED IN 21 CFR 1271.10

FEI: 3001503330

Other FDA Registrations: Blood:

Devices:
Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2022 Last Registration Receipt Date: 12/06/2021 Summary Report Print Date: 12/15/2021

Legal Name and Location:

California Transplant Services, Inc. dba SafetyGraft

5845 Owens Avenue

Carlsbad, California 92008

USA

Phone: 760-804-6890 Ext.: 101

Reporting Official:

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USA

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Satellite Recovery Establishment:

No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone							Х	Х	Х			SafetyGraft Autologous Bone
Cardiac Tissue - non-valved												
Cartilage							Х		Х			
Cornea							Х		Х			
Dura Mater												
Embryo												
Fascia							Х		Х			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							Х		Х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid										23-FEB-19		Autologous Parathyroid
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera							Х		Х			
Semen												
Skin							Х	Х	Х			Donor and Autologous Skin
Tendon							Х		Х			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.
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Proprietary Name(s):

FEI: 3001503330 Legal Name: California Transplant Services, Inc. dba SafetyGraft