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

Ext.: 101

FEI: 3001503330

Other FDA Registrations: Blood:

Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/14/2022 Summary Report Print Date: 12/15/2022

Legal Name and Location:

Carlsbad, California 92008

Phone: 760-804-6890

California Transplant Services, Inc. dba SafetyGraft

5845 Owens Avenue

USA

Marc Pablo, Sr. Vice President 5845 Owens Avenue Carlsbad, California 92008 USA

Reporting Official:

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

No

No

venue Testing For Micro-Organisms Only:

Phone: 760-804-6890 Ext. 101 mpablo@catransplant.org

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

Legal Name:

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This annual registration is for Storage and Distribution of homologous human tissue, recovered, tested, processed, released for distribution by FDA registered tissue establishments that are accredited by 1) American Association of Tissue Banks and/or 2) Eye Bank Association of America AND for Storage, Labeling and Distribution of hospital recovered autologous human bone and skin for re-implant in the same patient at a later date.

Proprietary Name(s):

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