

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: 3031886728	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/17/2024 Summary Report Print Date: 12/05/2024
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Legal Name and Location: Coast to Coast Donation LLC 2275 Rio Bonito Way, #150 San Diego, California 92108 USA Phone: 619-941-0141 Ext.:	Reporting Official: Grace M Centola, Tissue Bank Director 2275 Rio Bonito Way # 150 San Diego, California 92108 USA Phone: 585-683-1043 Ext. gcentola51@gmail.com	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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Directed		X									
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:

Coast to Coast Donation LLC will match a semen donor with a recipient, and perform the Donor Eligibility Determination (DED). All Screening, testing, physical exam, etc and cryopreservation and storage, as per regulations, will be performed under contract with a separate facility (Gen5 Fertility, San Diego, CA; FEI # 3014745310). Coast to Coast Donation LLC will review all documents and perform the DED and acceptance of each donor for clinical use with a matched recipient. Specimens will be distributed by the contracted facility upon order from the recipient's physician and Coast to Coast Donation LLC.

Proprietary Name(s):

FEI: 3031886728

Legal Name:

Coast to Coast Donation LLC