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: 3002133806

Other FDA Registrations: Blood: FEI: 0000002830 Devices:FEI: 0000002891

Drugs: FEI: 0000002656

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024

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

Legal Name and Location:

Gulf Coast Regional Blood Center 1400 La Concha

Reporting Official: Sharon L Garcia, Director of Quality Assurance 1400 La Concha

Houston, Texas 77054

Phone: 713-791-6657 Ext. sgarcia@giveblood.org

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)).

Houston, Texas 77054 USA

FEI:

3002133806

Phone: 713-790-1200

Ext.:

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

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3002133806 Legal Name: Gulf Coast Regional Blood Center