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.:

FEI: 3025981313

Other FDA Registrations: Blood:

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

Last Annual Registration Year: 2023
Last Registration Receipt Date: 01/27/2023
Summary Report Print Date: 01/27/2023

Legal Name and Location:

Eurofins CellTx, Inc. 9052 S Rita Rd Ste. 1400

USA

Tucson, Arizona 85747

Phone: 520-633-4125

Reporting Official:
Ronnie Aga, President ELE

9052 S Rita Rd Ste.1400

Tucson, Arizona 85747

USA

Phone: 303-704-9345 Ext. Quality@celltx.eurofinsus.com Satellite Recovery Establishment:

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)).

No

			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				Х								
Blood Vessel				X								
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo	Anonymous, Directed, SIP			х								
Fascia												
Heart Valve												
HPC Apheresis	Autologous, Family Related			х								
HPC Cord Blood	Autologous, Family Related			х								
Ligament												
Nerve Tissue				х								
Oocyte	Anonymous, Directed, SIP			х								
Ovarian Tissue				Х								
Pancreatic Islet Cells - autologous				х								
Parathyroid				Х								
Pericardium												
Peripheral Blood Mononuclear Cells	Autologous, Family Related			Х								
Peritoneal Membrane				Х								
Sclera												
Semen	Anonymous, Directed, SIP			х								
Skin												
Tendon												
Testicular Tissue				Х				<u> </u>				
Tooth Pulp				Х								
Umbilical Cord Tissue				Х								

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3025981313 Legal Name: Eurofins CellTx, Inc.