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: 3012046649

Other FDA Registrations: Blood:

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

Last Annual Registration Year: 2022 Last Registration Receipt Date: 12/10/2021 Summary Report Print Date: 12/15/2021

Legal Name and Location:

Miami, Florida 33167

Phone: 786-605-1533

USA

Legacy Donor Services Foundation 2430 NW 116th Street Juan P Rojas, VP of Quality Systems 2430 NW 116th Street

Bldg 3. Miami, Florida 33167

USA

Phone: 786-605-1533 Ext.

jrojas@vivex.com

Reporting Official:

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		Х	Х									
Bone		Х	Х									
Cardiac Tissue - non-valved												
Cartilage		X	Х									
Cornea			Х									
Dura Mater												
Embryo												
Fascia		X	Х									
Heart Valve		X	Х									
HPC Apheresis												
HPC Cord Blood												
Ligament		X	Х									
Nerve Tissue			Х									
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		Х	Х									
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera			Х									
Semen												
Skin		Х	Х									
Tendon		Х	Х									
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: N/A

Proprietary Name(s):

FEI: 3012046649 Legal Name: Legacy Donor Services Foundation