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: 3009510454

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:

Legacy Donor Services Foundation-Jacksonville

3901 University Boulevard, Suite 119

Jacksonville, Florida 32216

USA

Phone: 786-605-1533

Reporting Official:

Juan P Rojas, VP of Quality Systems

2430 NW 116th Street Miami, Florida 33167

Phone: 786-605-1533 Ext.

jrojas@vivex.com

Satellite Recovery Establishment: Yes

Parent Manufacturing Establishment FEI No.: 1000113913

Testing For Micro-Organisms Only:

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)).

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

Additional Information: N/A

Proprietary Name(s):

FEI: 3009510454 Legal Name: Legacy Donor Services Foundation-Jacksonville