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: 3009510454				Other FDA Registrations: Blood: Devices: Drugs:				Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/20/2023 Summary Report Print Date: 01/05/2024		
Legal Name and Location:				Reporting Official:							Satellite Recovery Establishment: Yes		
Legacy Donor Services Foundation-Jacksonville				Craig Sincaglia, VP of Quality Systems and Regulatory Aff							Parent Manufacturing Establishment FEI No.: 1000113913		
3901 University Boulevard, Suite 119			2430 NW 116th Street							Testing For Micro-Organisms Only: No			
			Miami, Florida 33167										
Jacksonville, Florida 32216 USA				USA Phone: 786-425-3634 Ext. csincaglia@vivex.com							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)).		
Phone: 786-425-3634 Ext.:										1271.27(0)).			
	L												
					nent Functio	ons							
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		x											
Bone		х					x						
Cardiac Tissue - non-valved													
Cartilage		х					x						
Cornea													
Dura Mater													
Embryo													
Fascia		х					х						
Heart Valve		х											
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					х						
Tendon		х					x						
Testicular Tissue													
Tooth Pulp													
Umbilical Cord Tissue													

Legal Name:

Additional Information: N/A

Proprietary Name(s):

FEI: 3009510454

Legal Name:

Legacy Donor Services Foundation-Jacksonville