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: 3000206983

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/20/2023 Summary Report Print Date: 12/01/2023

Legal Name and Location:

Lions World Vision Institute 1410 North 21st Street

Reporting Official:

Amandea Ridley-Dabney, Manager of Quality & Regulatory Affairs

1410 North 21st Street Tampa, Florida 33605

Phone: 813-289-1200 Ext. 310 amandea.r-dabney@lwvi.org

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

No

1271.27(b)).

Tampa, Florida 33605 USA

Phone: 813-289-1200

Ext.:

F110116. 013-203-1200 EAL.												
			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		X	Х		Х			Х				
Bone		х	Х		Х			Х				
Cardiac Tissue - non-valved		х	Х		Х			Х				
Cartilage		х	Х		Х			Х				
Cornea		х	Х		Х	Х	Х	Х	Х			
Dura Mater												
Embryo												
Fascia		х	Х		Х			Х				
Heart Valve		х	Х		Х			Х				
HPC Apheresis												
HPC Cord Blood												
Ligament		х	Х		Х			Х				
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		х	Х		Х			Х				
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		х	Х		Х	Х	Х	Х	Х			
Semen												
Skin		Х	Х		Х			Х				
Tendon		Х	Х		Х			Х				
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Proprietary Name(s):

FEI: 3000206983 Legal Name: Lions World Vision Institute