## DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

## FOOD AND DRUG ADMINISTRATION

Ext.:

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS **DESCRIBED IN 21 CFR 1271.10** 

FEI: 3003368882

Other FDA Registrations: Blood:

Devices:

Drugs:

Establishment Functions

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/20/2024 Summary Report Print Date: 01/10/2025

Legal Name and Location:

Lions World Vision Institute 2591 Bagylos Circle

Suite C-46

Bethlehem, Pennsylvania 18020

USA

Phone: 610-625-3800

Reporting Official:

Katrina D Capuzzo, Director of Quality Assurance

1200 6th Ave Ste 300

Seattle, Washington 98101

Phone: 206-838-4626 Ext. katrina.capuzzo@lwvi.org

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

١.	4:66	ional	Infor	matio	<b>n</b> .

Change of Name: Business License updated to add the registered trade name (dba) "Lions World Vision Institute"; license issued by State of Washington 10/27/2023.

Change of Address: Relocated from 2346 Jacksonville Rd at end of facility lease period to 2591 Bagylos Circle, Ste C-46, both in Bethlehem PA. Operations transitioned to new location 11/20/2023.

Proprietary Name(s):

FEI: 3003368882 Legal Name: Legal Name: Lions World Vision Institute