

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: 2023
Last Registration Receipt Date: 12/02/2022
Summary Report Print Date: 12/15/2022

Legal Name and Location:

Lions Eye Institute for Transplant and Research, Inc.
1410 North 21st Street

Tampa, Florida 33605
USA

Phone: 813-289-1200

Ext.:

Reporting Official:

Amandea Ridley-Dabney, Manager of Quality & Regulatory Affairs
1410 North 21st Street
Tampa, Florida 33605
USA
Phone: 813-289-1200 Ext. 310
aridley-dabney@lionseyeinstitute.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)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel		X	X		X				X			
Bone		X	X		X				X			
Cardiac Tissue - non-valved		X	X		X				X			
Cartilage		X	X		X				X			
Cornea		X	X		X	X	X	X	X			
Dura Mater												
Embryo												
Fascia		X	X		X				X			
Heart Valve		X	X		X				X			
HPC Apheresis												
HPC Cord Blood												
Ligament		X	X		X				X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		X	X		X				X			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		X	X		X	X	X	X	X			
Semen												
Skin		X	X		X				X			
Tendon		X	X		X				X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3000206983

Legal Name: Lions Eye Institute for Transplant and Research, Inc.