

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: 3011402906	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Change in Information Last Annual Registration Year: 2019 Last Registration Receipt Date: 12/04/2018 Summary Report Print Date: 12/19/2018
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Legal Name and Location: Lions Eye Institute for Transplant & Research, Inc. 4521 NW 6th Street Suite L Gainesville, Florida 32609 USA Phone: 813-289-1200 Ext.:	Reporting Official: Mikelanne Schipper, Director of Quality & Regulatory Affairs 1410 N. 21st Street Tampa, Florida 33605 USA Phone: 813-289-1200 Ext. mschipper@lionseyeinstitute.org 	Satellite Recovery Establishment: Yes Parent Manufacturing Establishment FEI No.: 3000206983 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)).
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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			
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			
Semen												
Skin		X	X		X				X			
Tendon		X	X		X				X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Change in address, November 2018.

Proprietary Name(s):