

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: 3012046568	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2018 Last Registration Receipt Date: 11/16/2017 Summary Report Print Date: 11/15/2018
--	------------------------	--	---

Legal Name and Location: Lions Eye Institute for Transplant & Research Inc. 12655 New Brittany Boulevard Suite 600 Fort Myers, Florida 33907 USA Phone: 813-289-1200 Ext.:	Reporting Official: Mikelanne V Schipper, Director of Quality & Regulatory Affairs 1410 North 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)).
--	---	--

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												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X			X				X			
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		X			X				X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):