

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,  TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS  DESCRIBED IN 21 CFR 1271.10</b>	<b>FEI:</b> 3015169808	<b>Other FDA Registrations:</b> <b>Blood:</b> <b>Devices:</b> <b>Drugs:</b>	Reason For Last Submission: Initial Registration/Listing Last Annual Registration Year: 2019 Last Registration Receipt Date: 11/16/2018 Summary Report Print Date: 03/01/2019
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<b>Legal Name and Location:</b> Lions Eye Institute for Transplant and Research 401 North Wickham Road Suite 141  Melbourne, Florida 32935 USA Phone: 813-289-1200 <b>Ext.:</b>	<b>Reporting Official:</b> Mikelanne Schipper, Director of Quality & Regulatory Affairs 1410 N. 21st Street Tampa, Florida 33605 USA Phone: 813-289-1200 Ext. mschipper@lionseyeinstitute.org	<b>Satellite Recovery Establishment:</b> Yes <b>Parent Manufacturing Establishment FEI No.:</b> 3000206983 <b>Testing For Micro-Organisms Only:</b> 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				
Bone		X			X			X				
Cardiac Tissue - non-valved		X			X			X				
Cartilage		X			X			X				
Cornea												
Dura Mater												
Embryo												
Fascia		X			X			X				
Heart Valve		X			X			X				
HPC Apheresis												
HPC Cord Blood												
Ligament		X			X			X				
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin		X			X			X				
Tendon		X			X			X				
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

**Additional Information:** LEITR assumed recovery operations in this office from RTI Surgical, an entity that was registered with FDA.

**Proprietary Name(s):**