

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: 3000718792	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2020 Last Registration Receipt Date: 11/18/2019 Summary Report Print Date: 12/10/2019
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Legal Name and Location: KLEB, Inc 1510 Newtown Pike Suite 140 Lexington, Kentucky 40511 USA Phone: 859-368-0957 Ext.:	Reporting Official: Nicole Wilson, Manager, QA & Regulatory Affairs 301 E. Muhammad Ali Blvd. Louisville, Kentucky 40202 USA Phone: 502-852-5457 Ext. nwilson@kylionseyebank.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)).
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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												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		X	X		X		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	X	X	X	X			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: Preparation of autologous serum eye drops.

Proprietary Name(s):

FEI: 3000718792

Legal Name:

KLEB, Inc