

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: 2026 Last Registration Receipt Date: 11/17/2025 Summary Report Print Date: 12/01/2025							
Legal Name and Location: KLEB, Inc 1510 Newtown Pike Suite 140 Lexington, Kentucky 40511 USA Phone: 859-368-0957 Ext:	Reporting Official: Brooke Hutcheson, QA/RA Coordinator 10160 Linn Station Road Louisville, Kentucky 40223 USA Phone: 502-290-5330 Ext. bhutcheson@ebky.org	Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: No Testing For Micro-Organisms Only: 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		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	
Semen										
Skin										
Tendon										
Testicular Tissue										
Tooth Pulp										
Umbilical Cord Tissue										

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3000718792

Legal Name:

KLEB, Inc