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HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION - Public Query

Establishment Details

Establishment Name and Location

Current Status: Registered

Last Annual Registration Year: 2026

FDA Establishment Identifier (FEI): 3013157033

Establishment Name: KLEB, Inc.

Address: 9115 Leesgate Rd
Suite A

City: Louisville

State: Kentucky

Zip: 40222

Country: UNITED STATES

Phone: 502-290-5330

Establishment Functions

Types of HCT/Ps	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute
Amniotic Membrane								
Blood Vessel								
Bone								
Cardiac Tissue - non-valved								
Cartilage								
Cornea	☒	☒		☒	☒	☒	☒	☒
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	☒	☒		☒	☒	☒	☒	☒
Semen								
Skin								

Tendon								
Testicular Tissue								
Tooth Pulp								
Umbilical Cord Tissue								

Establishment HCT/P Listing

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Proprietary Names
Amniotic Membrane		
Blood Vessel		
Bone		
Cardiac Tissue - non-valved		
Cartilage		
Cornea	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	
Semen		
Skin		
Tendon		
Testicular Tissue		
Tooth Pulp		
Umbilical Cord Tissue		

HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo					
HPC Apheresis					
HPC Cord Blood					
Oocyte					
Peripheral Blood Mononuclear Cells					
Semen					

Print Date: 09/18/2026

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