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

4745 Haven Point Blvd

Carmel, Indiana 46280

Phone: 317-808-5000

USA

FEI: 3000718320

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2024
Last Registration Receipt Date: 11/16/2023
Summary Report Print Date: 12/01/2023

 Legal Name and Location:
 Reporting Official:

 Indiana Lions Eye Bank, Inc.
 Alessandra Hamon

Ext.:

Alessandra Hamon, Quality Systems Manager 4745 Haven Point Blvd

Carmel, Indiana 46280

USA

Phone: 317-808-5000 Ext.

qa@visionfirst.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)).

		Establishment Functions										
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea		х	Х		X	X	Х	Х	Х			
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		х	Х		Х	Х	Х	Х	Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.
Additional information.	ino additional inionnation provided

Proprietary Name(s):

FEI: 3000718320 Legal Name: Indiana Lions Eye Bank, Inc.