

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: 3003103596

Other FDA Registrations:

Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2023
Last Registration Receipt Date: 12/07/2022
Summary Report Print Date: 12/15/2022

Legal Name and Location:

Indiana Organ Procurement Organization dba Indiana Donor Network
3760 Guion Road

Indianapolis, Indiana 46222
USA

Phone: 317-685-0389

Ext.:

Reporting Official:

Sarah E Lee, Manager, Regulatory Compliance
3760 Guion Road
Indianapolis, Indiana 46222
USA
Phone: 317-222-3407 Ext.
slee@indonornetwork.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)	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			X				
Bone		X	X		X		X	X				
Cardiac Tissue - non-valved		X	X		X			X				
Cartilage		X	X		X		X	X				
Cornea		X	X		X			X				
Dura Mater												
Embryo												
Fascia		X	X		X		X	X				
Heart Valve		X	X		X			X				
HPC Apheresis												
HPC Cord Blood												
Ligament		X	X		X		X	X				
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		X	X		X		X	X				
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		X	X		X			X				
Semen												
Skin		X	X		X		X	X				
Tendon		X	X		X		X	X				
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3003103596

Legal Name: Indiana Organ Procurement Organization dba Indiana Donor Network