## 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

Ext.:

FEI: 3001451643

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2021

Last Annual Registration Year: 2021
Last Registration Receipt Date: 11/17/2020
Summary Report Print Date: 11/30/2020

Legal Name and Location:

Gift of Hope Organ and Tissue Donor Network

425 Spring Lake Drive

JIO NEWOK

Itasca, Illinois 60143 USA

Phone: 630-758-2600

Reporting Official:

Shaun Martin, Director of Tissue Recovery Services

425 Spring Lake Drive Itasca, Illinois 60143

Phone: 630-758-2776 Ext. smartin@giftofhope.org

Satellite Recovery Establishment:

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)).

No

		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		Х	Х	Х								
Bone		Х	Х	X								
Cardiac Tissue - non-valved												
Cartilage		Х	Х	X								
Cornea		Х	Х	X								
Dura Mater												
Embryo												
Fascia		Х	Х	X								
Heart Valve		Х	Х	X								
HPC Apheresis												
HPC Cord Blood												
Ligament		Х	Х	Х								
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		Х	Х	Х								
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		Х	Х	Х								
Semen												
Skin		х	Х	X								
Tendon		х	Х	X								
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3001451643 Legal Name: Gift of Hope Organ and Tissue Donor Network