## 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

Reporting Official:

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Change in Information

Last Annual Registration Year: 2024 Last Registration Receipt Date: 01/04/2024 Summary Report Print Date: 01/05/2024

No

Legal Name and Location:

Gift of Hope Organ and Tissue Donor Network

425 Spring Lake Drive

USA

FEI:

Itasca, Illinois 60143

Phone: 630-758-2600

Itasca, Illinois 60143

Shaun Martin, Vice President, Tissue Operations 425 Spring Lake Drive

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)).

Establishment Functions Date of Date of Proprietary Name(s) HCT/P(s) Donor Type(s) Screen Donor Testina Package Process Store Distribute Label Resumption Discontinuance Amniotic Membrane Blood Vessel Х Χ Χ Χ Χ Bone Χ Х Cardiac Tissue - non-valved Cartilage Х Χ Х Cornea Dura Mater Embryo Fascia Χ Χ Х Heart Valve Х Х Х **HPC Apheresis** HPC Cord Blood Χ Х Ligament Х Nerve Tissue Х Oocyte Ovarian Tissue Pancreatic Islet Cells - autologous Parathyroid Pericardium Х Χ Χ Peripheral Blood Mononuclear Cells Peritoneal Membrane Х Sclera Semen Skin Х Χ Χ Tendon Х Х Х Testicular Tissue Tooth Pulp **Umbilical Cord Tissue** 

3001451643

Legal Name:

Additional Information:	No additional information provided.
Additional information.	reo additional information provided.

Proprietary Name(s):

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