## 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: 3013534653

Other FDA Registrations: Blood:

Devices:

Drugs:

Fatablish mant Freezie

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024
Last Registration Receipt Date: 11/29/2023
Summary Report Print Date: 12/01/2023

Legal Name and Location:

VisionGift dba Lions VisionGift 27-43 Wormwood Street

Boston, Massachusetts 02210

USA

Suite 100

Phone: 503-808-7026

Reporting Official:

Kristin Mathes, VP Quality Systems

27-43 Wormwood Street

Suite 100

Boston, Massachusetts 02210

USA

Phone: 503-808-7026 Ext. kristin@visiongift.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	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							Х		Х			
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera							Х		Х			
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3013534653 Legal Name: VisionGift