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: 3011694452

Other FDA Registrations: Blood:

Devices:

Drugs:

Fatablish mant Freezie

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 12/06/2022 Summary Report Print Date: 12/15/2022

No

Legal Name and Location:

National Jewish Health 1400 Jackson Street

Denver, Colorado 80206 USA

Phone: 800-550-6227

Ext.:

Reporting Official:

Ali Willey, Manager Quality Management

1400 Jackson Street Attn: Ali Willey Denver, Colorado 80206

Phone: 303-270-2778 Ext. WilleyA@NJHealth.org

Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: Yes

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

Additional Information:	No additional information provided.

Proprietary Name(s):

FEI: 3011694452 Legal Name: National Jewish Health