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: 3011694452

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2019 Last Registration Receipt Date: 11/27/2018 Summary Report Print Date: 12/19/2018

Legal Name and Location:

National Jewish Health 1400 Jackson Street Attn: Ronald Harbeck

Denver, Colorado 80206

USA

Phone: 303-398-1337

Reporting Official:

Lara Yourkin, Associate Executive Director

1400 Jackson Street Attn: Kari Caldwell Denver, Colorado 80206

Phone: 303-398-1133 Ext. yourkinl@njhealth.org

Satellite Recovery Establishment:

No

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)).

	Donor Type(s)	Establishment Functions										
HCT/P(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):

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