

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: 3010250935	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2021 Last Registration Receipt Date: 02/23/2021 Summary Report Print Date: 03/05/2021
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Legal Name and Location: The Sperm and Embryo Bank of New York, Inc. 13 East 37th Street, 4F New York, New York 10016 USA Phone: 212-531-0115 Ext.:	Reporting Official: Director 13 East 37th Street, 4F New York, New York 10016 USA Phone: Ext.	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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel												
Bone												
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo	SIP						X		X			
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte	SIP						X		X			
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous, Directed, SIP		X		X	X	X	X	X			
Skin												
Tendon												
Testicular Tissue			X		X	X	X	X	X			
Tooth Pulp												
Umbilical Cord Tissue												

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Legal Name and Location: BioGenetics Corporation 187 Mill Lane Mountainside, New Jersey 07092 USA Phone: 908-654-8836 Ext.:	Reporting Official: [Redacted] Director / CEO 187 Mill Lane Mountainside, New Jersey 07092 USA Phone: [Redacted] Ext.	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)).
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Amniotic Membrane												
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Bone												
Cardiac Tissue - non-valved												
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Cornea												
Dura Mater												
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Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Anonymous		X		X	X	X	X	X			
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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: 3003945123	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2021 Last Registration Receipt Date: 02/23/2021 Summary Report Print Date: 03/05/2021
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Legal Name and Location: The Sperm and Embryo Bank of NJ, Inc 187 Mill Lane Mountainside, New Jersey 07092 USA Phone: 908-232-6844 Ext.:	Reporting Official: Director / CEO 187 Mill Lane Mountainside, New Jersey 07092 USA Phone: [REDACTED] Ext.	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)).
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Amniotic Membrane												
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Cartilage												
Cornea												
Dura Mater												
Embryo	SIP						X		X			
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte	SIP						X		X			
Ovarian Tissue							X		X			
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	Directed, SIP		X		X	X	X	X	X			
Skin												
Tendon												
Testicular Tissue			X		X	X	X	X	X			
Tooth Pulp												
Umbilical Cord Tissue												

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: 3013695833

Other FDA Registrations:
Blood:
Devices:
Drugs:

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

Legal Name and Location:


CryoChoice, LLC
1777 Northeast Expressway NE
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Reporting Official:

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USA
Phone: 404-325-0907 Ext. 7000
contact@cryochoice.com

Satellite Recovery Establishment:

No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:

No

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Establishment Functions

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Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen	SIP	X	X					X	X	X		
Skin												
Tendon												
Testicular Tissue		X	X					X	X	X		
Tooth Pulp												
Umbilical Cord Tissue												