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: 3011402904

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: 12/13/2022 Summary Report Print Date: 12/15/2022

No

Legal Name and Location:

Cryos International USA LLC 2200 N Alafaya Trail

Suite 550

Orlando, Florida 32826

USA

Phone: 407-203-1175 **Ext.:** 5003

Reporting Official:

Corey Burke, Tissue Bank Director

2200 N Alafaya Trail

Suite 550

Orlando, Florida 32826

USA

Phone: 407-203-1175 Ext. cb@cryosinternational.com

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

Additional Information:	No additional
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No additional information provided.

Proprietary Name(s):

FEI: 3011402904

Legal Name:

Cryos International USA LLC