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: 3015036179

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/09/2024 Summary Report Print Date: 12/20/2024

Legal Name and Location:

Nicosia, CY-2373

Phone: 35722005676

CYPRUS

Cryos International - CyprusLtd Prigkipos Karolou 6 ¿ Ayios Dometios

Dixie Howell, Tissue Bank Director Andrology

2200 N. Alafaya Trail Suite 550

Reporting Official:

Orlando, Florida 32826

Phone: 407-203-1175 Ext. dhw@cryosinternational.com 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)).

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

Additional Information: No additional information provided.

Proprietary Name(s):

For Non U.S. Establishments Only: U.S. Agent(s):

Name and Organization	Address	Phone and Email		
Dixie C. Howell, MHA, Tissue Bank Director Andrology	2200 North Alafaya Trail, Ste 550, Orlando, Florida, USA 32826	407-203-1175-5003		
Cryos International USA		dhw@cryosinternational.com		
Importer(s): Name and Organization	Address	Phone and Email		
Matthew Rawlings	2200 North Alafaya Trail, Ste 550, Orlando, Florida 32826	407-203-1175		
Cryos International USA LLC		mra@cryosinternational.com		

El: 3015036179 Legal Name: Cryos International - CyprusLtd