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: 3001238470

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2025 Last Registration Receipt Date: 11/22/2024

Summary Report Print Date: 12/05/2024

Legal Name and Location:

LifeLink Foundation, Inc. d/b/a LifeLink of Puerto Rico Daimler-Chrysler Bldg./Metro Office Park

1 Calle 1, Suite 100

Guaynabo, 00968-1711 PUERTO RICO

Phone: 800-558-0977

Reporting Official:

Elizabeth S Horn-Brinson, VP, Regulatory Affairs and Lab Services

9661 Delaney Creek Boulevard

Tampa, Florida 33619

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

FEI:

Additional Information:	Additional Location:
	Rexco Industrial Park
	Lot #5 Road 165

Guaynabo, PR 00968

LifeLink of Puerto Rico is a division of LifeLink Foundation, Inc.

Proprietary Name(s):

FEI: 3001238470 LifeLink Foundation, Inc. d/b/a LifeLink of Puerto Rico