## 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: 3007353017

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: 11/22/2022
Summary Report Print Date: 12/01/2022

Legal Name and Location:

Joint Restoration Foundation DBA JRF Ortho

10962 Bigge Street

San Leandro, California 94577

USA

Phone: 877-255-6727

Reporting Official:

Dina Pasquino, Chief Compliance Officer

7245 S. Havana Street

Suite #300

Centennial, Colorado 80112

USA

Phone: 877-255-6727 Ext. dpasquino@jrfortho.org

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)).

No

		Establishment Functions										
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							Х		Х			
Cardiac Tissue - non-valved												
Cartilage							Х		Х			
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament							Х		Х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon							Х		Х			***See full text on next page.
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

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Proprietary Name(s):	Tendon	GraftLink® XL Tendon; PilotGraft BTB Tendon; SpeedGraft® Tendon; VersaGraft® Tendon; VersaGraft® 3.5 Tendon; SpeedGraft® Achilles Tendon

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Additional Information:

No additional information provided.