## 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: 3006185361

Other FDA Registrations: Blood:

Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/16/2023 Summary Report Print Date: 12/01/2023

No

Legal Name and Location:

Joint Restoration Foundation DBA JRF Ortho

7245 S. Havana Street Suite #300

Centennial, Colorado 80112 USA

Phone: 877-255-6727

Reporting Official:

Dina Pasquino, Chief Compliance Officer

7245 S. Havana Street

Suite #300

Centennial, Colorado 80112

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)).

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

Additional Informatio	n: No additional information provided.	
Proprietary Name(s):	Tendon	GraftLink® XL Tendon; PilotGraft BTB Tendon; SpeedGraft® Tendon; VersaGraft® Tendon; VersaGraft® 3.5 Tendon; SpeedGraft® Achilles Tendon

FEI: 3006185361 Legal Name: Joint Restoration Foundation DBA JRF Ortho