## DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

**DESCRIBED IN 21 CFR 1271.10** 

## FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Ext.:

FEI: 3007353017

Other FDA Registrations: Blood:

Devices: Drugs:

Fatablish mant Freezie

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

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<br>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               |               |                         |        |               |         |         |       |       |            |                        |                       |                                |

Legal Name:

| _                    |        |  |
|----------------------|--------|--|
| 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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|                      |        |  |

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Additional Information:

No additional information provided.