## 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: 3004586709

Other FDA Registrations: Blood: Devices:

Drugs:

Fatablish mant Frontier

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2025
Last Registration Receipt Date: 12/02/2024
Summary Report Print Date: 12/05/2024

No

Legal Name and Location:

ReproTech LLC

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Coconut Creek, Florida 33073

USA

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Reporting Official:

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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<br>Resumption | Proprietary Name(s) |
| Amniotic Membrane                   |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Blood Vessel                        |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Bone                                |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Cardiac Tissue - non-valved         |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Cartilage                           |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Cornea                              |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Dura Mater                          |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Embryo                              | Anonymous, Directed, SIP |                         |        |               |         |         | Х     | Х     | Х          |                        |                       |                     |
| Fascia                              |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Heart Valve                         |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| HPC Apheresis                       |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| HPC Cord Blood                      |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Ligament                            |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Nerve Tissue                        |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Oocyte                              | Anonymous, Directed, SIP |                         |        |               |         |         | Х     | Х     | Х          |                        |                       |                     |
| Ovarian Tissue                      |                          |                         |        |               |         |         | Х     | Х     | Х          |                        |                       |                     |
| Pancreatic Islet Cells - autologous |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Parathyroid                         |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Pericardium                         |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Peripheral Blood Mononuclear Cells  |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Peritoneal Membrane                 |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Sclera                              |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Semen                               | Anonymous, Directed, SIP |                         |        |               |         |         | Х     | Х     | Х          |                        |                       |                     |
| Skin                                |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Tendon                              |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Testicular Tissue                   |                          |                         |        |               |         |         | Х     | Х     | Х          |                        |                       |                     |
| Tooth Pulp                          |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |
| Umbilical Cord Tissue               |                          |                         |        |               |         |         |       |       |            |                        |                       |                     |

| Additional Information: | No additional information provided. |
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Proprietary Name(s):

FEI: 3004586709 Legal Name: ReproTech LLC