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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>PUBLIC HEALTH SERVICE<br>FOOD AND DRUG ADMINISTRATION<br><b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS,<br/> TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS<br/> DESCRIBED IN 21 CFR 1271.10</b> | <b>FEI:</b> 3006813973 | <b>Other FDA Registrations:</b><br><b>Blood:</b><br><b>Devices:</b> FEI: 3008812241<br><b>Drugs:</b> | Reason For Last Submission: Annual Registration/Listing<br>Last Annual Registration Year: 2025<br>Last Registration Receipt Date: 11/20/2024<br>Summary Report Print Date: 12/05/2024 |
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| <b>Legal Name and Location:</b><br><br>Musculoskeletal Transplant Foundation d/b/a/ MTF Biologics<br>1175 Mid Valley Drive<br><br><br>Olyphant, Pennsylvania 18447<br>USA<br><br>Phone: 570-496-3400 <b>Ext.:</b> | <b>Reporting Official:</b><br>Joel Osborne, Vice President, Regulatory Affairs<br>Attn: Joel Osborne<br>125 May Street Suite 300<br>Edison , New Jersey 08837<br>USA<br>Phone: 732-661-0202 Ext. ra_licenses@mtf.org | <b>Satellite Recovery Establishment:</b> No<br><b>Parent Manufacturing Establishment FEI No.:</b><br><b>Testing For Micro-Organisms Only:</b> No<br><br>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)). |
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| HCT/P(s)                            | Donor Type(s) | Establishment Functions |        |               |         |         |       |       |            | Date of Discontinuance | Date of Resumption | Proprietary Name(s)            |
|-------------------------------------|---------------|-------------------------|--------|---------------|---------|---------|-------|-------|------------|------------------------|--------------------|--------------------------------|
|                                     |               | Recover                 | Screen | Donor Testing | Package | Process | Store | Label | Distribute |                        |                    |                                |
| Amniotic Membrane                   |               |                         |        |               |         |         | X     |       | X          |                        |                    | ***See full text on next page. |
| Blood Vessel                        |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Bone                                |               |                         |        |               |         |         | X     |       | X          |                        |                    | ***See full text on next page. |
| Cardiac Tissue - non-valved         |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Cartilage                           |               |                         |        |               |         |         | X     |       | X          |                        |                    |                                |
| Cornea                              |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Dura Mater                          |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Embryo                              |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Fascia                              |               |                         |        |               |         |         | X     |       | X          |                        |                    |                                |
| Heart Valve                         |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| HPC Apheresis                       |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| HPC Cord Blood                      |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Ligament                            |               |                         |        |               |         |         | X     |       | X          |                        |                    |                                |
| Nerve Tissue                        |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Oocyte                              |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Ovarian Tissue                      |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Pancreatic Islet Cells - autologous |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Parathyroid                         |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Pericardium                         |               |                         |        |               |         |         | X     |       | X          |                        |                    |                                |
| Peripheral Blood Mononuclear Cells  |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Peritoneal Membrane                 |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Sclera                              |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Semen                               |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Skin                                |               |                         |        |               |         |         | X     |       | X          |                        |                    | ***See full text on next page. |
| Tendon                              |               |                         |        |               |         |         | X     |       | X          |                        |                    |                                |
| Testicular Tissue                   |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Tooth Pulp                          |               |                         |        |               |         |         |       |       |            |                        |                    |                                |
| Umbilical Cord Tissue               |               |                         |        |               |         |         |       |       |            | 31-MAY-21              |                    |                                |

**Additional Information:** No additional information provided.

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| <b>Proprietary Name(s):</b> Amniotic Membrane | AmnioBand Viable, Salera Mini Membrane, VersaShield, Enhance, Blockade, Essence, AmnioBand Matrix, AmnioBand, AmnioBand Viable Membrane, Amnioclear, Revitalon, Placental Matrix , Salera Membrane   |
| Bone  | Conform Sheet, Luminary CC-ALIF, Luminary T-PLIF, ARCH ODL, VerteFill, Conform Flex, Conform Cube, Trinity Evolution, Trinity ELITE, Luminary PLIF, Cartilage Allograft Matrix, AlloAid Cartilage Matrix, Prime DBM , Oracle, Profile, AlloQuent, CartiMax , Prime HD DBM, DBX Natural Fiber Strip , MOPS, Allio, AlloAid Cartilage Matrix, AlloAid Evans Wedge, AlloAid Cotton Wedge, AlloAid SubChon, AlloAid QF Cortical, AlloAid Backfill Plug, Vallos Granules, Vallos f Demineralized Cortical Fibers, Vallos Demin Cortical, Cartimax FA, Threaded Facet Dowel, fiberFUSE Advanced, fiberFUSE Strip, Kore Fiber Moldable, Kore Fiber Strip, Allofiber DBF, BAC: Biologic Allograft Chain, Prolix, MTF Fiber, MTF Fiber Strip, Virtuos, AlloAid PIP, AlloAid DIP |
| Skin  | FlexHD Pliable, FlexHD Pliable Perforated, FlexHD Pliable Shaped, FlexHD Structural, FlexHD Structural Diamond, AlloPatch Pliable, AlloPatchHD, Allopatch Pliable Meshed, PerioDerm , FlexHD Pliable MAX, FlexHD Pliable PRE, SomaGen , RenuvaHD, Leneva, Renuva, Allograft Adipose Matrix , AlloAid Dermal Matrix, AlloAid Dermal Meshed Matrix   |

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