## 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: 3002719998

Other FDA Registrations:

Blood:

Devices:FEI: 3002719998

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2022 Last Registration Receipt Date: 11/29/2021 Summary Report Print Date: 12/01/2021

Legal Name and Location:

RTI Surgical, Inc. (also dba RTI Biologics, Inc.)

11621 Research Circle

Alachua, Florida 32615

USA

FEI:

3002719998

Phone: 386-418-8888

Reporting Official:

Amanda LoGuidice, Director Research and Development

11621 Research Circle Alachua, Florida 32615

USA

Phone: 716-413-9202 Ext. aloguidice@rtix.com

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

No

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

|                      | Distracting, and Puros. |   |
|----------------------|-------------------------|---|
| Proprietary Name(s): | Skin                    | Axis, Allomax, Cortiva, Matrix HD, Puros, Tutoplast |
|                      |                         |   |

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Bone Proprietary Names - AlloCraft, AlloPure, AlloQuent, AlloWedge, BioAdapt, BioCleanse, Bio DBM Boat, Bio DBM Putty, Bio DBM Shape, BioSet, Bigfoot, CeSpace, Cornerstone,

Cross-Fuse, Divergence, Elemax, FacetFix, LinQ SI, MDII, Optefii, Opteform, Pocket and Shaped Strip, Pure Strip, Synergent, Optio-C, RegenaVate, Tutoplast, SR, Capistrano, Self-

Additional Information: