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| 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 | FEI: 3002719998 | Other FDA Registrations: Blood: Devices: FEI: 3002719998 Drugs: | Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2020 Last Registration Receipt Date: 12/12/2019 Summary Report Print Date: 01/07/2020 |
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| Legal Name and Location: RTI Surgical, Inc. (also dba RTI Biologics, Inc.) 11621 Research Circle Alachua, Florida 32615 USA Phone: 386-418-8888 Ext.: | Reporting Official: Kerry K Pearson, Director Operations Quality 11621 Research Circle Alachua, Florida 32615 USA Phone: 386-418-8888 Ext. 4111 kpearson@rtix.com | Satellite Recovery Establishment: No 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)). |
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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 | | | | | | | | | | | | |
| Blood Vessel | | | | | | | | | | | | |
| Bone | | | | | X | X | X | X | X | | | See additional listing |
| Cardiac Tissue - non-valved | | | | | | | | | | | | |
| Cartilage | | | | | X | X | X | X | X | | | |
| Cornea | | | | | X | X | X | X | X | | | Tutoplast |
| Dura Mater | | | | | | | | | | | | |
| Embryo | | | | | | | | | | | | |
| Fascia | | | | | X | X | X | X | X | | | Suspend, Tutoplast |
| Heart Valve | | | | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | | | | X | X | X | X | X | | | BioCleanse |
| Nerve Tissue | | | | | | | | | | | | |
| Oocyte | | | | | | | | | | | | |
| Ovarian Tissue | | | | | | | | | | | | |
| Pancreatic Islet Cells - autologous | | | | | | | | | | | | |
| Parathyroid | | | | | | | | | | | | |
| Pericardium | | | | | X | X | X | X | X | | | Puros, Tutoplast |
| Peripheral Blood Mononuclear Cells | | | | | | | | | | | | |
| Peritoneal Membrane | | | | | | | | | | | | |
| Sclera | | | | | X | X | X | X | X | | | Tutoplast |
| Semen | | | | | | | | | | | | |
| Skin | | | | | X | X | X | X | X | | | ***See full text on next page. |
| Tendon | | | | | X | X | X | X | X | | | BioCleanse, Select |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | |

Additional Information: Bone Proprietary Names - AlloCraft, AlloPure, AlloQuent, AlloWedge, BioAdapt, BioCleanse, Bio DBM Boat, Bio DBM Putty, Bio DBM Shape, BioSet, BioReady, Bigfoot, CeSpace, CoreLink DBM Putty, CoreLink DBM Crush Mix, Cornerstone, Cross-Fuse, Divergence, Elemax, FacetFix, MDII, Optefil, Opteform, Pocket and Shaped Strip, Pure Strip, Synergent, Optio-C, RegenaVate, Tutoplast, SR, Capistrano, Self-Distracting, and Puros.

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