

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: 2021 Last Registration Receipt Date: 11/24/2020 Summary Report Print Date: 11/30/2020
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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: Matthew Winton, Director Operations Quality 11621 Research Circle Alachua, Florida 32615 USA Phone: 828-234-5459 Ext. 4111 mwinton@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.

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