

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: 2024 Last Registration Receipt Date: 11/15/2023 Summary Report Print Date: 12/01/2023						
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: Amanda LoGuidice, Vice President, QA, RA, Product Science 11621 Research Circle Alachua, Florida 32615 USA Phone: 716-413-9202 Ext. aloguidice@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)).						
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	X			See additional listing
Cardiac Tissue - non-valved												
Cartilage			X		X	X	X	X	X			
Cornea			X		X	X	X	X	X			Tutoplast
Dura Mater												
Embryo												
Fascia			X		X	X	X	X	X			Suspend, Tutoplast
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			X		X	X	X	X	X			BioCleanse
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium			X		X	X	X	X	X			Puros, Tutoplast
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera			X		X	X	X	X	X			Tutoplast
Semen												
Skin			X		X	X	X	X	X			***See full text on next page.
Tendon			X		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, Bigfoot, CeSpace, Cornerstone, Cross-Fuse, Divergence, Elemax, FacetFix, LinQ SI, MDII, Optefil, Opteform, Pocket and Shaped Strip, Pure Strip, Synergent, Optio-C, RegenerOss, RegenaVate, Tutoplast, SR, Capistrano, Self-Distracting, and Puros.

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