

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: 2026 Last Registration Receipt Date: 11/18/2025 Summary Report Print Date: 12/01/2025
--	------------------------	--	---

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: Rose Lopez, Vice President, Quality Assurance 11621 Research Circle Alachua, Florida 32615 USA Phone: 386-418-5188 Ext. rlopez@evergenbio.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			X									
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, AlloGr8, allOoss, 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, Magnus® Ultra Viable Cellular Allograft, MDII, Optefil, Opteform, OsteoPearl Biological Allograft, Pocket and Shaped Strip, Pure Strip, Synergent, Optio-C, Raptos Jar, RegenerOss, RegenaVate, Tutoplast, SR, Capistrano, Self-Distracting, and Puros.

Proprietary Name(s):	Skin	Axis, Allomax, Cortiva, Derm-Maxx Dermal Matrix Fenestrated, Derm-Maxx Dermal Matrix Non-Fenestrated, Matrix HD, Matrix HD Allograft Dermis, Matrix HD Allograft Dermis Non-Fenestrated, Puros, Tutoplast
-----------------------------	------	---

FEI:3002719998

Legal Name:RTI Surgical, Inc. (also dba RTI Biologics, Inc.)