

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

<b>Legal Name and Location:</b> RTI Surgical, Inc. (also dba RTI Biologics, Inc.) 11621 Research Circle  Alachua, Florida 32615 USA Phone: 386-418-8888		<b>Reporting Official:</b> Rose Lopez, Vice President, Quality Assurance 11621 Research Circle Alachua, Florida 32615 USA Phone: 386-418-5188 Ext. rlopez@evergenbio.com	<b>Satellite Recovery Establishment:</b> No <b>Parent Manufacturing Establishment FEI No.:</b> <b>Testing For Micro-Organisms Only:</b> No
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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	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, alloOoss, 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
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