

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: 3002924436	Other FDA Registrations: Blood: Devices: FEI: 3002924436 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: Tutogen Medical GmbH, a wholly owned subsidiary of RTI Surgical, Inc. (also dba R Industriestra Be 6 D-91077 Neunkirchen am. Brand Neunkirchen, 91077 GERMANY Phone: 49 9134 99 88 0 Ext.: 0	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				Puros
Cardiac Tissue - non-valved												
Cartilage					X	X	X	X				Tutoplast
Cornea												
Dura Mater												
Embryo												
Fascia					X	X	X	X				Tutoplast
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium					X	X	X	X				Puros, Tutoplast
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin					X	X	X	X				Puros, Tutoplast
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

For Non U.S. Establishments Only:

U.S. Agent(s):

Name and Organization	Address	Phone and Email
Rose Lopez, Vice President, Quality Assurance RTI Surgical, Inc.	11621 Research Circle, Alachua, Florida, USA 32615	386-418-5188 rlopez@rtix.com

Importer(s):

Name and Organization	Address	Phone and Email
RTI Surgical, Inc. RTI Surgical, Inc.	11621 Research Cir, Alachua, Florida 32615	386-418-8888 aloguidice@rtix.com
RTI Surgical, Inc. RTI Surgical, Inc.	11621 Research Circle, Alachua, Florida 32615	386-418-8888 aloguidice@rtix.com
RTI Surgical, Inc. RTI Surgical, Inc.	11621 Research Cir, Alachua, Florida 32615	386-418-8888 rlopez@rtix.com
RTI Surgical, Inc. RTI Surgical, Inc.	11621 Research Cir, Alachua, Florida 32615	386-418-8888 rlopez@evergenbio.com

FEI: 3002924436

Legal Name: Tutogen Medical GmbH, a wholly owned subsidiary of RTI Surgical, Inc.
(also dba RTI Biologics, Inc.)