

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
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