

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: 2020
Last Registration Receipt Date: 12/12/2019
Summary Report Print Date: 01/07/2020

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: 09134-99-88-8 5

Ext.: 0

Reporting Official:

Kerry K Pearson, Director of Quality
11621 Research Circle
Alachua, Florida 32615
USA
Phone: 386-418-8888 Ext. 4111
kpearson@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				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
Kerry K. Pearson, Director of Quality RTI Surgical, Inc.	11621 Research Circle, Alachua, Florida, USA 32615	386-418-8888-4111 kpearson@rtix.com

Importer(s):

Name and Organization	Address	Phone and Email
Kerry K. Pearson RTI Surgical, Inc.	11621 Research Circle, Alachua, Florida 32615	386-418-8888 kpearson@rtix.com

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(also dba RTI Biologics, Inc.)