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Annual Registration Successful

Facility: RTI Surgical, Inc. (dba RTI Biologics, Inc.), ALACHUA, Florida, UNITED STATES

You have successfully updated your registration and listing information for 2026.

Your registration will be valid through Dec 31, 2026.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2026.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 1641375.

Facility Information

Registration Number:

3002719998

Initial Importer:

Y

Facility Name:

RTI Surgical, Inc. (dba RTI Biologics, Inc.)

Legal Name:

Address:

**11621 Research Circle,
ALACHUA, Florida, 32615, UNITED STATES**

DUNS Number:

117560455

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s):

1. RTI Biologics, Inc.
2. Regeneration Technologies, Inc.

Establishment located on a campus:

Owner/Operator Information

Owner/Operator Number:

1641375

Contact Name:
 Amanda LoGuidice
Company:
 RTI SURGICAL, INC. (DBA RTI BIOLOGICS, INC.)
Address: 11621 Research Circle
 Alachua, FLORIDA, 32615, UNITED STATES
Telephone:
 386 - 4188888 - 4832
Fax:
 386 - 5186596
E-mail: accreditation@rtix.com
DUNS Number:

Official Correspondent Information

Contact Name:
 Amanda LoGuidice
Company:
 RTI SURGICAL, INC. (DBA RTI BIOLOGICS, INC.)
Address: 11621 Research Circle
 Alachua, FLORIDA, 32615, UNITED STATES
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Device Listings

Listing Number	Premarket Submission Number	Premarket Submission Type	Product Code(s)	Device Name(s)	Activities
D168944		510(k) exempt	HXY	BRACE, DRILL	Specification Developer
D064855	K080418		NUN	BONE GRAFTING MATERIAL, HUMAN SOURCE	Manufacturer
D064856	K072327		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D064857	K063584		HWC	Screw, fixation, bone	Manufacturer
			JDR	Staple, fixation, bone	

D277701	K142070		OXF	Mesh, surgical, absorbable, plastic and reconstructive surgery	Specification Developer
			FTM	Mesh, surgical	
D064858	K060180		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
			MBP	Filler, bone void, osteoinduction (w/o human growth factor)	
D064859	K060253		HWC	Screw, fixation, bone	Manufacturer
D199568		510(k) exempt	GFI	OSTEOTOME, MANUAL	Specification Developer
D064863	K051615		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D064864	K050767		HWC	Screw, fixation, bone	Manufacturer
D064866	K043421		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D064867	K043420		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D080251		510(k) exempt	FTY	TAPE, MEASURING, RULERS AND CALIPERS	Specification Developer
D064868		510(k) exempt	FSM	TRAY, SURGICAL, INSTRUMENT	Specification Developer
D080253		510(k) exempt	HTO	REAMER	Specification Developer
D199555		510(k) exempt	HXL	MALLET	Specification Developer
D064861	K052405		HWC	Screw, fixation, bone	Manufacturer
D113302		510(k) exempt	FZT	CUTTER, SURGICAL	Specification Developer
D080191		510(k) exempt	HTJ	GAUGE, DEPTH	Specification Developer

D192140	K123356		FTM	Mesh, surgical	Specification Developer
D080190		510(k) exempt	HTR	RASP	Specification Developer
D080197		510(k) exempt	HXD	CLAMP	Specification Developer
D055949	K073097		NPL	Barrier, animal source, intraoral	Specification Developer
D080188		510(k) exempt	FZX	Guide, surgical, instrument	Specification Developer
D080189		510(k) exempt	HTW	BIT, DRILL	Specification Developer
D080186	K081538		DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	Specification Developer
			PAJ	Mesh, surgical, non-synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed	
			FTM	Mesh, surgical	
			OXH	Mesh, surgical, collagen, plastic and reconstructive surgery	
D515172	K230036		GAT	Suture, nonabsorbable, synthetic, polyethylene	Manufacturer
D196885		510(k) exempt	GFG	BIT, SURGICAL	Specification Developer
D216057	K132850		GXQ	DURA SUBSTITUTE	Specification Developer
D064875		510(k) exempt	HWX	TAP, BONE	Specification Developer
D064877		510(k) exempt	GAF	SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY	Repackager/Relabeler

D064879		510(k) exempt	EID	SYRINGE, RESTORATIVE AND IMPRESSION MATERIAL	Repackager/Relabeler
D064870		510(k) exempt	HXX	SCREWDRIVER	Specification Developer Repackager/Relabeler
D064872		510(k) exempt	HXI	PASSER, WIRE, ORTHOPEDIC	Specification Developer
D064881		510(k) exempt	LXH	Orthopedic manual surgical instrument	Specification Developer
D064883		510(k) exempt	HXG	TAMP	Specification Developer

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
Tutogen Medical GmbH	Industriestrasse 6, Neunkirchen am Brand, Bavaria, D- 91077, GERMANY	NPL	Barrier, animal source, intraoral	K073097
Tutogen Medical GmbH	Industriestrasse 6, Neunkirchen am Brand, Bavaria, D- 91077, GERMANY	FTM	Mesh, surgical	K091142
Tutogen Medical GmbH	Industriestrasse 6, Neunkirchen am Brand, Bavaria, D- 91077, GERMANY	FTM	Mesh, surgical	K123356
Tutogen Medical GmbH	Industriestrasse 6, Neunkirchen am Brand, Bavaria, D- 91077, GERMANY	GXQ	DURA SUBSTITUTE	K132850

Tutogen Medical GmbH	Industriestrasse 6, Neunkirchen am Brand, Bavaria, D-91077, GERMANY	DXZ	PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	K991296
		PAJ	Mesh, surgical, non-synthetic, urogynecologic, for apical vaginal and uterine prolapse, transabdominally placed	
		FTM	Mesh, surgical	
		OXH	Mesh, surgical, collagen, plastic and reconstructive surgery	

Date of Initial Registration: 2008-12-02 14:24:52.0