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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 2021.

Your registration will be valid through Dec 31, 2021.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2021.

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.)

Address:

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

DUNS Number:

014520584

Foreign Trade Zone:

N

Facility URL:

Other Business Trade Name(s):

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

Owner/Operator Information

Owner/Operator Number:
1641375

Contact Name:
Christine Thomas

Company:
RTI SURGICAL, INC. (DBA RTI BIOLOGICS, INC.)

Address: 11621 Research Circle
Alachua, FLORIDA, 32615, UNITED STATES

Telephone:
715 - 8219262

Fax:
386 - 5186596

E-mail: cthomas@rtix.com

DUNS Number:

Official Correspondent Information

Contact Name:
Christine Thomas

Company:
RTI SURGICAL, INC. (DBA RTI BIOLOGICS, INC.)

Address: 11621 Research Circle
Alachua, FLORIDA, 32615, UNITED STATES

Telephone:
715 - 8219262

Fax:
386 - 5186596

E-mail: cthomas@rtix.com

DUNS Number:

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D168944	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	

D064858	K060180	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
		MBP	Filler, bone void, osteoinduction (w/o human growth factor)	
D277701	K142070	OXF	Mesh, surgical, absorbable, plastic and reconstructive surgery	Specification Developer
		FTM	Mesh, surgical	
D064859	K060253	HWC	Screw, fixation, bone	Manufacturer
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
D064868	Exempt	FSM	TRAY, SURGICAL, INSTRUMENT	Specification Developer Manufacturer
D080251	Exempt	FTY	TAPE, MEASURING, RULERS AND CALIPERS	Repackager/Relabeler
D080253	Exempt	HTO	REAMER	Specification Developer Manufacturer
D064861	K052405	HWC	Screw, fixation, bone	Manufacturer
D113302	Exempt	FZT	CUTTER, SURGICAL	Specification Developer
D080191	Exempt	HTJ	GAUGE, DEPTH	Repackager/Relabeler
D192140	K123356	FTM	Mesh, surgical	Specification Developer
D080190	Exempt	HTR	RASP	Repackager/Relabeler
D080197	Exempt	HXD	CLAMP	Specification Developer Repackager/Relabeler
D055949	K073097	NPL	Barrier, animal source, intraoral	Specification Developer
D080188	Exempt	FZX	Guide, surgical, instrument	Specification Developer Repackager/Relabeler Manufacturer

D080189	Exempt	HTW	BIT, DRILL	Repackager/Relabeler
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	
D196885	Exempt	GFG	BIT, SURGICAL	Specification Developer Manufacturer
D216057	K132850	GXQ	DURA SUBSTITUTE	Specification Developer
D064875	Exempt	HWX	TAP, BONE	Specification Developer
D064877	Exempt	GAF	SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY	Repackager/Relabeler
D064879	Exempt	EID	SYRINGE, RESTORATIVE AND IMPRESSION MATERIAL	Repackager/Relabeler
D064870	Exempt	HXX	SCREWDRIVER	Specification Developer
				Repackager/Relabeler
D064872	Exempt	HXI	PASSER, WIRE, ORTHOPEDIC	Repackager/Relabeler
D064881	Exempt	LXH	ORTHOPEDIC MANUAL SURGICAL INSTRUMENT	Repackager/Relabeler Specification Developer
D064883	Exempt	HXG	TAMP	Manufacturer
				Specification Developer

Imported Products and Manufacturers

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