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Annual Re-Registration
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FACILITY: RTI BIOLOGICS, INC., ALACHUA, FLORIDA, UNITED STATES

You have successfully updated your registration and listing information for 2012.

Your registration will be valid through Dec 31, 2012.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2012.

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

Facility

Registration Number: 3002719998
Initial Importer: Y
Facility Name: RTI Biologics, Inc.
Address: 11621 RESEARCH CIR.
ALACHUA, Florida, 32615, UNITED STATES
Facility URL:
Other Business Trade Name(s): 1. Regeneration Technologies, Inc.

Owner/Operator Information

Contact Name: Caroline A Hartill
Company: RTI BIOLOGICS, INC.
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Official Correspondent Information

Contact Name: CHERYL L BAGWELL
 Company: RTI Biologics, Inc.
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 Alachua, FLORIDA, 32615, UNITED STATES
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 E-mail: cbagwell@rtix.com

Device Listings

Listing Number	Premarket Submission Number	Product Codes	Device Name	Activities
D055949	K073097	NPL	Barrier, animal source, intraoral	Specification Developer
D064866	K043421	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D064870	Exempt	HXX	SCREWDRIVER	Specification Developer Repackager/Relabeler
D080253	Exempt	HTO	REAMER	Repackager/Relabeler
D064861	K052405	HWC	SCREW, FIXATION, BONE	Manufacturer
D080190	Exempt	HTR	RASP	Repackager/Relabeler
D080251	Exempt	FTY	TAPE, MEASURING, RULERS AND CALIPERS	Repackager/Relabeler
E379268	K991296	FTM	MESH, SURGICAL	Specification Developer
D064857	K063584	JDR	STAPLE, FIXATION, BONE	Manufacturer
		HWC	SCREW, FIXATION, BONE	
D064883	Exempt	HXG	TAMP	Specification Developer Manufacturer
D064858	K060180	MBP	Filler, bone void, osteoinduction (w/o human growth factor)	Manufacturer
		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	
D064864	K050767	HWC	SCREW, FIXATION, BONE	Manufacturer
D064875	Exempt	HWX	TAP, BONE	Specification Developer
D080186	K081538	FTM	MESH, SURGICAL	Specification Developer
		MFJ	Vessel guard or cover, to facilitate revision surgeries	
D080191	Exempt	HTJ	GAUGE, DEPTH	Repackager/Relabeler
D064859	K060253	HWC	SCREW, FIXATION, BONE	Manufacturer
D080187	Exempt	JDZ	MIXER, CEMENT, FOR CLINICAL USE	

				Repackager/Relabeler
D080185	K072238	MPB	CATHETER, HEMODIALYSIS, NON-IMPLANTED	Manufacturer
		MQV	FILLER, BONE VOID, CALCIUM COMPOUND	
D064856	K072327	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D064863	K051615	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D064868	Exempt	FSM	TRAY, SURGICAL, INSTRUMENT	Repackager/Relabeler Specification Developer
D064879	Exempt	EID	SYRINGE, RESTORATIVE AND IMPRESSION MATERIAL	Repackager/Relabeler
D113302	Exempt	FZT	CUTTER, SURGICAL	Specification Developer
D064855	K080418	NUN	BONE GRAFTING MATERIAL, HUMAN SOURCE	Manufacturer
D080188	Exempt	FZX	GUIDE, SURGICAL, INSTRUMENT	Repackager/Relabeler
D064877	Exempt	GAF	SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY	Repackager/Relabeler
D080189	Exempt	HTW	BIT, DRILL	Repackager/Relabeler
D080197	Exempt	HXD	CLAMP	Repackager/Relabeler
D064867	K043420	MQV	FILLER, BONE VOID, CALCIUM COMPOUND	Manufacturer
D064881	Exempt	LXH	ORTHOPEDIC MANUAL SURGICAL INSTRUMENT	Manufacturer Specification Developer

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

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