DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2015

Resorba Medical GmbH
% Mr. Karl Beck
Quality Assurance/Regulatory Affairs Manager
Am Flachmoor 16
90475 Nürnberg
Germany

Re: K143584
Trade/Device Name: PGA RESORBA, PGA RESOQUICK, GLYCOLON
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 23, 2015
Received: September 28, 2015

Dear Mr. Beck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part

807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
unknown

Device Name
GLYCOLON
Absorbable poly(glycolide/l-lactide) surgical suture

Indications for Use *(Describe)*
GLYCOLON® is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
unknown

Device Name
PGA resorba
Absorbable poly(glycolide/l-lactide) surgical suture

Indications for Use *(Describe)*
PGA RESORBA® is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not in cardiovascular surgery or neural tissue.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
unknown

Device Name
PGA resoquick
Absorbable poly(glycolide/l-lactide) surgical suture

Indications for Use *(Describe)*
PGA resoquick™ is indicated for use in general soft tissue approximation, including ophthalmic (e.g. conjunctiva) procedures, but not in cardiovascular or neurological procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5.0 TRADITIONAL 510(K) SUMMARY

Submitted by: Resorba Medical GmbH
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Germany
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Contact Person: Karl-Josef Beck/Rose Guang

Date of Summary: 30 October 2015

Trade Name	Common Name	Classification Name	Regulation Classification	Product Code	Class of device	Predicate device
PGA RESORBA®	Suture, absorbable, synthetic, polyglycolic acid	Absorbable poly(glycolide/l-lactide) surgical suture	21 CFR §878.4493	GAM	II	Surgisorb, Samyang K984374
PGA Resoquick™	Suture, absorbable, synthetic, polyglycolic acid	Absorbable poly(glycolide/l-lactide) surgical suture	21 CFR §878.4493	GAM	II	Safil Quick, Aesculap K011372 *Surgisorb, Samyang K984374 *Optime Peters Surgical K062366
GLYCOLON®	Suture, absorbable, synthetic, polyglycolic acid	Absorbable poly(glycolide/l-lactide) surgical suture	21 CFR §878.4493	GAM	II	Monocryl Ethicon K960653

*Secondary predicates

Device Description: The subject devices are synthetic absorbable surgical sutures.

	PGA Resorba	**PGA resoquick**	**Glycolon**
Primary material	Polyglycolic acid (PGA)	Polyglycolic acid (PGA)	Copolymer glycolide and Ɛ-caprolactone (PGA/CL)
Material presentation	Multifilament, braided	Multifilament, braided	Monofilament
Dyed or undyed	Undyed and dyed D&C violet No.2	Undyed	Undyed and dyed D&C violet No.2
Coated or uncoated	Coated Polycaprolactone + calcium stearate	Coated Polycaprolactone + calcium stearate	Uncoated
Suture material is a sterile, flexible, thread offered in a variety of lengths, reels, range of diameters, with or without needles attached.	Yes	Yes	Yes

Indication for Use: PGA RESORBA® is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not in cardiovascular surgery or neural tissue.

PGA resoquick™ is indicated for use in general soft tissue approximation, including ophthalmic (e.g. conjunctiva) procedures, but not in cardiovascular or neurological procedures.

GLYCOLON® is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

Substantial Equivalence: Each absorbable suture has the same intended use and similar design, materials, labeling, performance characteristics to their predicate device.

Technological characteristics

Each absorbable suture is substantially equivalent to the predicate device listed when compared to the technological characteristics and are supplied sterile for single use. All meet USP requirements except for minor variations in diameter for Glycolon® monofilament absorbable suture.

Comparison of technological characteristics to predicate device:

	Intended use	**Material**	**Design**	**Performance** **Diameter/ Needle attachment/ Tensile strength**
PGA RESORBA	Indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not in cardiovascular surgery or neural tissue	Material: Polyglycolic acid (PGA) Coating: Polycaprolactone + calcium stearate Dye: D&C violet No.2	Absorbable, multifilament, dyed, coated, provided sterile with or without needles	Meets U.S.P
Predicate	Same	Same	Same	Same
PGA RESOQUICK	Indicated for use in general soft tissue approximation, including ophthalmic (e.g. conjunctiva) procedures, but not in cardiovascular or neurological procedures.	Material: Polyglycolic acid (PGA) Coating: Polycaprolactone + calcium stearate Dye: undyed	Absorbable, multifilament, undyed, coated, provided sterile with or without needles	Meets U.S.P
Predicate	Same	Similar, different coating	Same	Same
Secondary predicates	Same	Same	Same	Same
GLYCOLON	Indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or	Material: glycolide and Ɛ-caprolactone (PGA/CL) Coating: Uncoated	Absorbable, monofilament, dyed, uncoated, provided sterile with or without needles	Meets U.S.P except for diameter

	ophthalmic surgery.	Dye: D&C violet No.2		
Predicate	Same	Same	Same	Same

Performance Testing Summary:

As per the FDA's Class II Special Control Guidance Document for Surgical Sutures, the devices were subjected to the requirements of the United States Pharmacopeia (U.S.P) monograph for Synthetic Absorbable Sutures. Testing included:

- Diameter <861>
- Tensile strength <881>
- Needle attachment <871>

Resorption profiles have been evaluated for each material. Resorption data in-vitro and in-vivo were provided for PGA Resorba, Glycolon and in-vivo only for PGA resoquick.

Results of USP performance and resorption testing demonstrate that each absorbable suture meets the current USP performance requirements for absorbable sutures (with the exception of GLYCOLON® that has minor variations in diameter from USP) and they are substantially equivalent to each corresponding predicate device listed.

Biocompatibility evaluation in accordance with ISO 10993-1 has been supported for each material by leveraging data from each supplier and each material having an established history of use for the same intended use.

Conclusion

Based on the information provided within this 510(k) submission, Resorba Medical GmbH concludes that the proposed suture products are substantially equivalent to each corresponding predicate device listed.