September 18, 2018

Resorba Medical GmbH
c/o Ms. Helen Topping
Regulatory Affairs Manager
Am Flachmoor 16
90475 Nürnberg
Germany

Re: K181320
Trade/Device Name: CAPROLON®
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: July 18, 2018
Received: July 23, 2018

Dear Ms. Topping:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181320

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

Indications for Use *(Describe)*
CAPROLON® is Indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and 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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510(k) Summary Statement

Submitted by:	Resorba Medical GmbH Am Flachmoor 16 90475 Nuremberg Germany Tel: +49 9128-9115-0 Fax: +49 9128-9115-10
Contact Person:	Helen Topping
Date of Summary:	16th May 2018
Trade Name	CAPROLON®
Common Name	Suture, absorbable, synthetic, polyglycolic acid
Classification Name	Absorbable poly(glycolide/l-lactide) surgical suture
Regulation Classification	21 CFR §878.4493
Product Code	GAM
Class of device	II
Predicate device	Monograms Gramsmed K010672
Reference Predicate	PDS II Ethicon N18331

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Device Description:

CAPROLON® is a synthetic absorbable surgical suture.

- Primary material is Poly(L-lactide-co-ε-caprolactone), P(LA/CL)
- Material presentation is Monofilament
- Undyed and dyed (D&C violet No.2) variants
- Coated with a mixture of calcium stearate and the copolymer of L-lactide and Ɛ-caprolactone
- Suture material is a sterile, flexible, thread offered in a variety of lengths (35cm to 90cm), reels, range of diameters (USP 7-0 to 2), with or without needles attached.

Indication for Use:

CAPROLON® is Indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Substantial Equivalence:

CAPROLON® has the same intended use and similar design, materials, labeling, performance characteristics to its predicate device

Technological characteristics

CAPROLON® is substantially equivalent to the predicate device listed when compared to the technological characteristics of primary material, material presentation, dye, coating and are supplied sterile for single use. All meet USP requirements except for variations in diameter. The subject and predicate sutures are manufactured from the identical material from the same material supplier.

Comparison of technological characteristics to predicate device:

Characteristic	**CAPROLON®**	**Monograms K010672**
Intended Use	Indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures	Same
Material	Material: Poly(L-lactide-co-ε-caprolactone) P(LA/CL) Coating:	Same

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	mixture of calcium stearate and the copolymer of L-lactide and Ɛ-caprolactone Dye: D&C violet No.2	
Design	Absorbable, monofilament, dyed, uncoated, provided sterile with or without needles	Same
Sizes	Supplied in a range of USP sizes	Same
Performance Diameter/ Needle attachment/ Tensile strength	Meets U.S.P except for diameter	Same
Sterilization	Ethylene Oxide	Same

Performance Testing Summary:

As per the FDA's Class II Special Control Guidance Document for Surgical Sutures, the subject device was 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 profile from in-vitro and in-vivo testing and published data has been evaluated.

Stability testing has been completed.

Results of USP performance and resorption testing demonstrate that the subject device meets USP performance requirements for absorbable sutures with the exception of minor variations in diameter from USP and is substantially equivalent to the predicate device listed.

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Biocompatibility evaluation in accordance with ISO 10993-1 has been supported by testing on the final subject device or design and process equivalent devices.

Conclusion

Based on the information provided within this 510(k) submission, Resorba Medical GmbH concludes that the CAPROLON® is substantially equivalent to the predicate device listed.