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

October 29, 2015

Resorba Medical GmbH
Mr. Karl-Josef Beck
Quality Assurance/Regulatory Affairs Manager
Am Flachmoor 16
Nuremberg, 90475 Germany

Re: K143582
Trade/Device Name: MOPYLEN, RESOPREN, SILK, POLYESTER, NYLON, RESOLON, POLYAMIDE PSEUDO, STEEL
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW, MXW, GAP, GAT, GAR, GAQ
Dated: September 2, 2015
Received: September 8, 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" (21CFR 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.

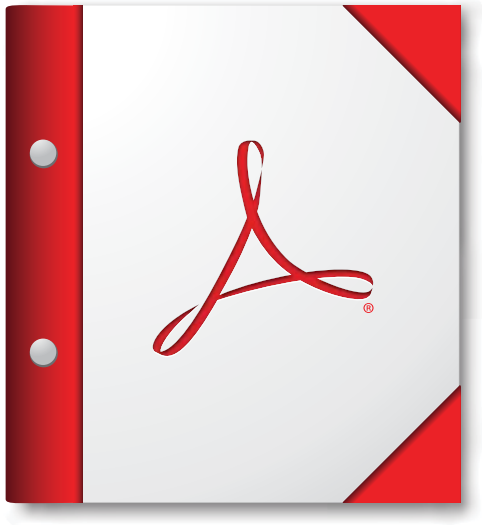
You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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



For the best experience, open this PDF portfolio in Acrobat X or Adobe Reader X, or later.

Get Adobe Reader Now!

5.0 TRADITIONAL 510(K) SUMMARY

Submitted by: Resorba Medical GmbH
Am Flachmoor 16
90475 Nuremberg
Germany
Tel: +49 9128-9115-0
Fax: +49 9128-9115-10

Contact Person: Karl-Josef Beck

Date of Summary: 01 September 2015

Trade Name	Common Name	Classification Name	Regulation Classification	Product Code	Class of device	Predicate device
MOPYLEN®	Non absorbable suture: Polypropylene	Nonabsorbable polypropylene surgical suture	21 CFR §878.5010	GAW	II	Premilene, Aesculap, K980703
RESOPREN®	Non absorbable suture: Polyvinylidene diflouride	Nonabsorbable polypropylene surgical suture	21 CFR §878.5010	MXW	II	Pronova, Ethicon, K001625
SILK	Non absorbable suture: Silk	Natural nonabsorbable silk surgical suture	21 CFR §878.5030	GAP	II	Silkam, Aesculap, K990089 Secondary predicate1: Riversilk Riverpoint Medical K100006 Secondary predicate2: WG-Surgical Foosin Medical supplies Inc. K080684
POLYESTER	Non absorbable suture: Polyester	Nonabsorbable poly(ethylene terephthalate) surgical suture	21 CFR §878.5000	GAT	II	Cottony II, Tevdek K021019
NYLON	Non absorbable suture: Polyamide	Nonabsorbable polyamide surgical suture	21 CFR §878.5020	GAR	II	Dermalon, Davis&Geck, K981582

RESOLON®	Non absorbable suture: Polyamide	Nonabsorbable polyamide surgical suture	21 CFR §878.5020	GAR	II	Cardionyl, Promedica K913102
POLYAMIDE PSEUDO	Non absorbable suture: Polyamide	Nonabsorbable polyamide surgical suture	21 CFR §878.5020	GAR	II	Supramid, S Jackson, K904052 Secondary predicate: Dermalon, Davis&Geck, K981582
STAINLESS STEEL	Non absorbable suture: Steel	Stainless Steel suture	21 CFR §878.4495	GAQ	II	Flexon, Davis&Geck, K955723 Secondary predicate1: FerroFibre Pontis Orthopaedics LLC K140127 Secondary predicate 2: Stainless steel medical suture CP Medical inc. K030351

Device Description: The subject devices are non-absorbable surgical sutures. They are available undyed and dyed. The sutures are supplied sterile, in monofilament, twisted and braided forms in sizes USP 11-0 to 7 (depending on suture type), with or without needles in a variety of cut lengths.

Description	Primary material	Form	Colour and Colourant for primary material	Coating	Sizes (USP)
MOPYLEN	Polypropylene (PP)	Monofilament	Blue (Phthalocyaninato{2}) copper	None	10-0 to 2
RESOPREN	Polyvinylidene diflouride (PVDF)	Monofilament	Blue (Phthalocyaninato{2}) copper	None	8-0 to1
SILK	Silk Bombyx Mori L.	Braided	Black Logwood Extract	Silicone	10-0 to 6
			White Undyed	Silicone	10-0 to 6
POLYESTER	Polyester (PET)	Braided	White Undyed	None	7-0 to 7
			Green D&C Green	None	
NYLON	Polyamide 6-6.6(PA)	Monofilament	White Undyed	None	11.0 to 2
			Black Logwood Extract	None	11.0 to 2
RESOLON	Polyamide 6-6.6(PA)	Monofilament	Blue (Phthalocyaninato{2}) copper	None	11-0 to 2
POLYAMIDE PSEUDO	Polyamide 6-6.6(PA) With polyamide 6 sheath	Monofilament or twisted with polyamide sheath	White Undyed	None	7-0 to 7
STEEL	Stainless Steel 1.4404 - AISI 316 L	Monofilament or twisted	NA	None	6.0 to 7

Indication for Use: Each non-absorbable suture is used as a surgical suture to support wound closure/soft tissue approximation, with the following indications:

Except Steel, each non-absorbable suture is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures*.

*MOPYLEN is also indicated for microsurgery
* POLYESTER is also indicated for orthopaedic surgery
*RESOLON is also indicated for microsurgery

Steel wire is indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.

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

Technological characteristics Each Non-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.

Comparison of technological characteristics to predicate device:

	Intended use	Material	Design	Performance Diameter, Needle attachment and Tensile strength	Sterilisation method
MOPYLEN	Intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, microsurgery, ophthalmic and neurological procedures.	Material: Polypropylene Coating: None Dye: (Phthalocyanato{2}) copper	Non-absorbable, monofilament, dyed, uncoated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Same	Same	Same	Same	Same

RESOPREN	Intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.	Material: Polyvinylidene diflouride Coating: None Dye: (Phthalocyanato{2}) copper	Non-absorbable, monofilament, dyed, uncoated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Same	Same	Same	Same	Same
SILK	Intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.	Material: Silk Bombyx Mori Coating: Silicone Dye: Logwood Extract	Non-absorbable, multifilament, dyed and undyed, coated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Same	Same	Same	Same	Gamma
Each Secondary predicate	Same	Same	Same	Same	Same
POLYESTER	Intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, orthopaedic, ophthalmic and neurological procedures.	Material: Polyester Coating: None Dye: D&C Green	Non-absorbable, multifilament, dyed and undyed, uncoated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Same	Same	Same	Same	Same

NYLON	Intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures	Material: Polyamide Coating: None Dye: Logwood Extract	Non-absorbable, monofilament, dyed and undyed, uncoated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Same	Same	Same	Same	Same
RESOLON	Intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, microsurgery and neurological procedures.	Material: Polyamide Coating: None Dye: (Phthalocyanato{2}) copper	Non-absorbable, monofilament, dyed, uncoated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Same	Same	Same	Same	Same
POLYAMIDE PSEUDO	Intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic and neurological procedures.	Material: Polyamide with polyamide sheath Coating: None Dye: Undyed	Non-absorbable, multifilament with sheath or monofilament undyed, uncoated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Intended for use in general soft tissue approximation and/or ligation including use in ophthalmic procedures	Same	Same	Same	Same
Secondary Predicate	Same	Same	Similar. Monofilament, no polyamide	Same	Same

			sheath.		
STAINLESS STEEL	Indicated for use in abdominal wound closure, hernia repair, sternal closure and orthopaedic procedures including cerclage and tendon repair.	Steel 316L	Non-absorbable, monofilament or twisted, undyed, uncoated, provided sterile with or without needles	Meets U.S.P	Ethylene Oxide
Predicate	Same	Same	Same	Same	Gamma
Each Secondary predicate	Same	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 Non-absorbable Sutures. Testing included:

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

Biocompatibility evaluation has been performed in accordance with ISO 10993-1, sensitization according to ISO 10993-10, implantation according to ISO 10993-6, data has also been leveraged from the supplier for Mopylen and Resopren. Rabbit pyrogen and LAL testing has successfully been performed on each subject device. Steel suture complies with ASTM F138-13. Real-time stability testing has been performed to support shelf life. With this data, an established history of use in non-US markets and results of performance testing it is demonstrated that each Non-absorbable suture meets the current performance requirements for Non-absorbable sutures and that it is substantially equivalent to each corresponding predicate device listed.

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.