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

June 8, 2017

Aesculap, Incorporated
Ms. Kathy A. Racosky
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K170661
Trade/Device Name: Novosyn Quick Absorbable Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: May 10, 2017
Received: May 11, 2017

Dear Ms. Racosky:

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,

Jennifer R. Stevenson -S3

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)*
K170661

Device Name
Novosyn Quick Absorbable Suture

Indications for Use *(Describe)*

Novosyn Quick Absorbable Suture is indicated for use in general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. Novosyn Quick suture is not intended for use in ligation in ophthalmic, 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.

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."

510(k) SUMMARY (as required by 21 CFR 807.92)

Aesculap Novosyn Quick Absorbable Suture
March 2, 2017

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com

TRADE NAME: Novosyn Quick Absorbable Suture

COMMON NAME: Synthetic Polyglycolic Absorbable Suture

CLASSIFICATION: Class II

CLASSIFICATION NAME: Suture, Absorbable, synthetic, Polyglycolic Acid

REGULATION NUMBER: 878.4493

PRODUCT CODE: GAM

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the Novosyn Quick Absorbable Suture.

PREDICATE DEVICE

- Primary Predicate: Novosyn Absorbable Suture, Aesculap Inc. (K122734)
- Vicryl Rapid Suture, Ethicon Inc. (K962480/K944110)

DEVICE DESCRIPTION

Novosyn Quick is a synthetic absorbable braided surgical suture which is supplied sterile. Novosyn Quick is composed of a copolymer made from 90% gylcolide and 10% L-lactide (PGLA). The Novosyn Quick suture is coated with 35/65 poly(glycolide-co-L-lactide) and calcium stearate. The Novosyn Quick suture is undyed and will be offered in diameters ranging from USP size 6-0 through 2. It will be available in a variety of cut lengths with or without needles attached.

INDICATIONS FOR USE

Novosyn Quick Absorbable Suture is indicated for use in general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. Novosyn Quick suture is not intended for use in ligation in ophthalmic, cardiovascular or neurological procedures.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

As established in this submission, the Novosyn Quick suture is a synthetic absorbable braided surgical suture offered undyed in the same range of diameters and cut lengths that are substantially equivalent to other predicate devices cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in design, intended use, material composition, function and range of sizes. The device characteristics comparing the Novosyn Quick Absorbable Suture to the predicate devices are summarized below.

	Aesculap, Inc. Novosyn Quick Absorbable Suture	**Primary Predicate Aesculap, Inc. Novosyn Absorbable Suture**	**Ethicon, Inc. Vicryl Rapide Suture**
K#	Pending	K122734	K962480/K944110
Indications	Novosyn Quick Absorbable Suture is indicated for use in general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. Novosyn Quick suture is not intended for use in ligation in ophthalmic, cardiovascular or neurological procedures.	Novosyn sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological tissues.	Vicryl Rapide suture is indicated only for use in superficial general soft tissue approximation of the skin and mucosa, where only short term wound support (7-10 days) is required. Vicryl rapide suture is not intended for use in ligation, ophthalmic, cardiovascular or neurological procedures.
Absorption Type	Short term absorbable	Mid term absorbable	Short term absorbable
Absorption	Essentially complete by 42 days	Essentially completed between 8-10 weeks	Essentially complete by 42 days
Remaining Tensile Strength	5 days 50% 14 days 0%	2 weeks 75% (6-0 and larger) 2 weeks 56% (7-0 and smaller) 3 weeks 52% (6-0 and larger) 3 weeks 35 % (7-0 and smaller) 4 weeks 23 % (5-0 and larger)	5 days 50% 14 days 0%
Material	Polyglycolide-co-L-lactid 90/10 (PGLA)	Polyglycolide-co-L-lactid 90/10 (PGLA)	Polyglactin 910 (glycolic and lactic acid)
Dyed, Un-dyed	Un-dyed	Un-dyed and Dyed	Un-dyed
Structure	Braided	Braided	Braided
Coating	Polyglycolide-co-L-lactid 35/65 + Calcium Stearate	Polyglycolide-co-L-lactid 35/65 + Calcium Stearate	Caproloctone / Glycolide + Polyglactin 370 (glycolide/lactide) w/ Calcium Stearate
Size	6-0 through 2 (various lengths) with or w/out needles attached	8-0 through 2 (various lengths) with or w/out needles attached	6-0 through 0 (various lengths) with or w/out needles attached

	Aesculap, Inc. Novosyn Quick Absorbable Suture	**Primary Predicate Aesculap, Inc. Novosyn Absorbable Suture**	**Ethicon, Inc. Vicryl Rapide Suture**
K#	Pending	K122734	K962480/K944110
Thread length	-45 cm to 150 cm -ligature reels of longer length	-5 cm to 150 cm -ligature reels of longer length	-45cm to 135cm
Physical: - Diameter - Length - Needle Attachment - Tensile Strength	All characteristics meet USP Requirements, except for diameter.	All characteristics meet USP Requirements, except for diameter.	All characteristics meet USP Requirements, except for diameter.
Needle material	300 stainless steel	300 stainless steel	unknown
Packaging	Foil packaging in a second outer peel-pack with paper and plastic film	Foil packaging in a second outer peel-pack with paper and plastic film	unknown
Sterilization	Gamma irradiation	Ethylene Oxide (EO)	Ethylene Oxide (EO) or Gamma Irradiation

PERFORMANCE DATA

As recommended by the FDA's Class II Special Control Guidance Document for Surgical Sutures, including mechanical testing in accordance to USP 39 for synthetic absorbable suture, biocompatibility testing in accordance to ISO 10993-1, and *in vitro* as well as *in vivo* resorption testing has been performed to demonstrate that the Novosyn Quick Absorbable Suture meets current performance requirements for synthetic absorbable sutures unless otherwise labeled, and that Novosyn Quick is substantially equivalent to other predicate devices.

Tests were conducted for diameter, tensile strength, and needle attachment. All specifications were met apart from diameter. The Novosyn Quick suture is considered an implant device, tissue/bone contact device of permanent duration (>30 days). Biocompatibility testing within this submission includes the following: Cytotoxicity, Sensitization, Intracutaneous Irritation, Acute Systemic Toxicity, Hemolysis, Genotoxicity – Chromosomal Aberration and Mouse Peripheral Blood Micronucleus, Bacterial Reverse Mutation and Muscle Implantation (6-week).

Testing demonstrated that the device is as safe and as effective as the predicate device. The subject device is concluded to be substantially equivalent to the predicate device.

The Novosyn Quick Absorbable Suture is blister packed and sterilized by Gamma. Real-time aging data for the Novosyn Quick Suture has been generated to support this submission.