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 23, 2017

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

Re: K171001
Trade/Device Name: Monosyn Quick Synthetic Absorbable Surgical Suture
Regulation Number: 21 CFR 878.4493
Regulation Name: Absorbable Poly(Glycolide/L-Lactide) Surgical Suture
Regulatory Class: Class II
Product Code: GAM
Dated: September 12, 2017
Received: September 13, 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 (DICE) 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 (DICE) 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,

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

510(k) Premarket Notification

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Monosyn Quick Synthetic Absorbable Surgical

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

510(k) Number *(if known)*

K171001

Device Name

Aesculap Monosyn Quick Synthetic Absorbable Surgical Suture

Indications for Use *(Describe)*

Monosyn Quick Synthetic Absorbable Surgical Suture is intended for general soft tissue approximation of the skin and mucosa, where only short term wound support (6-7 days) is required. Monosyn Quick suture is not indicated for use in cardiovascular or neurosurgery.

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

Aesculap Monosyn Quick Synthetic Absorbable Surgical Suture
September 12, 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: Monosyn Quick Synthetic Absorbable Surgical Suture

COMMON NAME: Synthetic Absorbable Surgical Suture

CLASSIFICATION: Class II

CLASSIFICATION NAME: Absorbable poly(glycolide/l-lactide) surgical suture

REGULATION NUMBER: 878.4493

PRODUCT CODE: GAM

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the Monosyn Quick Synthetic Absorbable Surgical Suture.

PREDICATE DEVICE

- Primary predicate: Monosyn Synthetic Absorbable Surgical Suture (K011375)
- Reference predicate: Caprosyn Absorbable Surgical Suture (K032586)

DEVICE DESCRIPTION

Monosyn Quick is an absorbable flexible monofilament suture which is supplied sterile. It is composed of a synthetic polyglycolic acid-based copolymer. The Monosyn Quick suture is undyed and will be offered in diameters ranging from USP size 6-0 through 1. It is uncoated and will be available in a variety of cut lengths with or with out needles attached.

INDICATIONS FOR USE

Monosyn Quick Synthetic Absorbable Surgical Suture is intended for general soft tissue approximation of the skin and mucosa, where only short term wound support (6-7 days) is required. Monosyn Quick suture is not indicated for use in cardiovascular or neurosurgery.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

As established in this submission, the Monosyn Quick suture is a synthetic absorbable monofilament 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 Monosyn Quick Synthetic Absorbable Surgical Suture to the predicate devices are summarized below.

	Aesculap Inc. Monosyn Quick Synthetic Absorbable Surgical Suture	**Aesculap, Inc. Monosyn Synthetic Absorbable Surgical Suture**	**United States Surgical Caprosyn Absorbable Surgical Suture**
K#	Proposed device	K011375	K032586
Indications	Monosyn Quick Synthetic Absorbable Surgical Suture is intended for general soft tissue approximation of the skin and mucosa, where only short term wound support (6-7 days) is required. Monosyn Quick suture is not indicated for use in cardiovascular or neurosurgery.	Monosyn Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological surgery.	Caprosyn synthetic absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular or neurological surgery, or microsurgery.
Absorption Type	Short term absorbable	Mid term absorbable	Short term absorbable
Absorption	Essentially complete by 56 days	Essentially completed between 60-90 days	Essentially complete by 56 days
Remaining Tensile Strength	5 days 60-70% 10 days 25-35%	14 days 50%	5 days 60% 10 days 20-30%
Material	72% glycolide 14% ε-caprolctone 14% trimethylene carbonate	72% glycolide 14% ε-caprolctone 14% trimethylene carbonate	Glycolide, Caprolactone, Trimethylene Carbonate and Lactide
Dyed, Un-dyed	Undyed	Un-dyed and Dyed	Un-dyed and Dyed
Structure	Monofilament	Monofilament	Monofilament
Size	6-0 through 1 (various lengths) with or w/out needles attached	5-0 through 1 (various lengths) with or w/out needles attached	6-0 through 1 (various lengths) with or w/out needles attached
Thread length	-45 cm to 120 cm	-35 cm to 150 cm -ligature reels of longer length	-18 in to 60 in -ligature reels of longer length
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 or 400 series stainless steel	300 or 400 series stainless steel	unknown

	Aesculap Inc. Monosyn Quick Synthetic Absorbable Surgical Suture	Aesculap, Inc. Monosyn Synthetic Absorbable Surgical Suture	United States Surgical Caprosyn Absorbable Surgical Suture
K#	Pending	K011375	K032589
Packaging	Coated cardboard support in double peel pouch. Inner pouch composed of PET, aluminum foil and LDPE layers. Medical grade paper and PET/LDPE laminate outer pouch. or Oval HDPE support with a coated cardboard lid in a single pouch composed of polyethylene terephthalate polyester (PETP). or cardboard support fold card in a single pouch composed of polyethylene terephthalate polyester (PETP).	Coated cardboard support in double peel pouch. Inner pouch composed of PET, aluminum foil and LDPE layers. Medical grade paper and PET/LDPE laminate outer pouch.	unknown
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	unknown

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 Monosyn Quick Synthetic Absorbable Surgical Suture meets current performance requirements for synthetic absorbable sutures unless otherwise labeled, and that Monosyn Quick is substantially equivalent to other predicate devices. The test results demonstrate that the Monosyn Quick complies with the following standards:

USP 39 Monograph for Absorbable Surgical Sutures
USP 39 <861> *Sutures – Diameter* (where diameter deviates minimally from USP requirements, it will be labeled as such)
USP 39 <881> *Tensile Strength*
USP 39 <871> *Sutures – Needle Attachment*
ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. (Biocompatibility)
ISO 10993-5, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
ISO 10993-6 2007, Biological Evaluation Of Medical Devices - Part 6: Tests For Local Effects After Implantation
ISO 10993-7, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals
ISO 10993-10 2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

ISO 10993-11 2006, Biological Evaluation Of Medical Devices - Part 11: Tests For Systemic Toxicity
ISO 11135-1:2007, Sterilization of health care products- Ethylene oxide- Part 1: Requirements for development, validation and routing control of a sterilization process for medical devices

The Monosyn Quick Synthetic Absorbable Surgical Suture is blister packed and sterilized by Ethylene Oxide. Accelerated aging data for the Monosyn Quick has been generated to support this submission.

CONCLUSION:
Non clinical testing demonstrated that the device is as safe, as effective, and performs as well as the predicate devices.

In addition, residual strength and absorption rate studies were performed. The results of this testing demonstrates that the Monosyn Quick is substantially equivalent to the predicate devices.