March 7, 2018

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

Re: K180321
Trade/Device Name: Aesculap Optilene Nonabsorbable Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable Polypropylene Surgical Suture
Regulatory Class: Class II
Product Code: GAW
Dated: February 5, 2018
Received: February 5, 2018

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.

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.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K180321

Device Name
Aesculap Optilene Nonabsorbable Surgical Suture

Indications for Use *(Describe)*

Optilene Nonabsorbable Polypropylene/Polyethylene Surgical sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and 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.

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

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

Aesculap Monosyn Synthetic Absorbable Surgical Suture
February 5, 2018

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.racoskv@acscula p.com

TRADE NAME: Aesculap Optilene Nonabsorbable Suture

COMMON NAME: Nonabsorbable polypropylene/polyethylene surgical suture

CLASSIFICATION: Class II

CLASSIFICATION NAME: Nonabsorbable polypropylene surgical suture

REGULATION NUMBER: 878.5010

PRODUCT CODE: GAW

PREDICATE DEVICE

- Optilene Nonabsorbable Surgical Suture (Kl33890)

DEVICE DESCRIPTION

Optilene is a nonabsorbable monofilament surgical suture which is supplied sterile. Optilene is composed of 95% polypropylene and 5% polyethylene. The Optilene suture is offered dyed with the FDA approved colorant [Phthalacyaninato(2-)] copper in accordance with Title 21 CFR, §74.3045. The Optilene suture previously ranged in diameters from USP size 10-0 through 0 in lengths ranging from 8 cm to 150 cm. The Optilene suture is offered with or without needles attached. The Optilene sutures are also offered with or without pledgets composed of 100% polytetrafluorothylene (PTFE). The pledgets are available separately packaged six per pouch.

The purpose of this submission is to seek clearance for a line extension to the Optilene Nonabsorbable Surgical Suture (Kl33890). This submission proposes two additional USP sizes, size 1 and 2 and to extend the length range to 240 cm.

INDICATIONS FOR USE

Optilene Nonabsorbable Polypropylene/Polyethylene Surgical sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.

SUBSTANTIAL EQUIVALENCE and COMPARISON OF TECHNOLICAL CHARACTERISTICS

The Optilene Nonabsorbable Surgical Suture line extension is as safe an effective as the previously cleared Optilene Nonabsorbable Surgical Suture. The proposed additional USP sizes, size 1 and 2, and suture lengths up to 240 cm to the Optilene Nonabsorbable Surgical Suture (K133890) product line have the same material, design, intended use and technological characteristics as the predicate device. The only difference between the proposed and predicate device is the suture diameter and length. The device characteristics comparing the Optilene Nonabsorbable Surgical Suture to the predicate device are summarized below.

	Aesculap Inc. Optilene Nonabsorbable Surgical Suture	Aesculap, Inc. Optilene Nonabsorbable Surgical Suture
K#	Predicate device (K133890)	Pronosed device
Indications	Indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.	Sarne
Material	95% oolypronvlene and 5% Polyethylene	Same
Colorant	fPhthalacyaninato(2-)l conner	Same
Dved	Yes	Sarne
Structure	Monofilament	Same
Size	USP I0-0 through 0 with or w/out needles attached with or w/out oledgets attached	USP l & 2 same san1e
Thread length	-8 cm to 150 cm -ligature reels oflon•er len'"h	-8 cm to 240 cm -li!!ature reels of lon.2'.er len£Jth
Physical: - Diameter - Length - Needle Attachment - Tensile Stremrth	All characteristics meet USP	Same
Needle material	300 series stainless steel	Same
Pled!!ets	oolvtetrafluoroethvlene	Same
Packaging	Oval HDPE support with an oval card fold card lid in a tyvek peel pouch and oolvester-oolvethvlenereohatalate film.	Same
Sterilization	Ethylene Oxide (EO)	Same

PERFORMANCE DATA

Performance tests: Non-clinical laboratory performance testing was conducted to verify that the Optilene Nonabsorbable Surgical Suture, USP sizes I and 2 conforms to the USP monograph for nonabsorbable sutures (as applicable). This testing was performed in accordance with FDA's Class II Special Controls Guidance Document: Surgical Sutures, Issued June 3, 2003. Materials used were evaluated per ISO 10993-1.

The test results demonstrate that proposed device complies with the following standards:

USP 40 Monograph for Nonabsorbable Surgical Sutures
USP 40 <861> *Sutures - Diameter*
USP 40 <881> *Tensile Strength*
USP 40 <871> *Sutures - Needle Attachment*

CONCLUSION:

The information provided in this submission demonstrates that the Optilene Nonabsorbable Surgical Suture line extension is substantially equivalent to the marketed predicate device.