JUL 15 2014

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

Aesculap Optilene Nonabsorbable Surgical Suture
July 3, 2014

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: Aesculap Optilene Nonabsorbable Suture

COMMON NAME: Nonabsorbable polypropylene/polyethylene surgical suture

CLASSIFICATION: Class II

CLASSIFICATION NAME: Suture, Nonabsorbable, Synthetic, Polypropylene

REGULATION NUMBER: 878.5010

PRODUCT CODE: GAW

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Optilene Nonabsorbable Polypropylene/Polyethylene Surgical Suture is substantially equivalent to:

- Premilene Nonabsorbable Polypropylene Surgical Suture, Aesculap Inc. (K980703)
- Prolene Polypropylene Nonabsorbable Surgical Suture, Ethicon Inc. (N16374)
- USS Polypropylene Suture, United States Surgical (K050947/K010909/K954808)

The Optilene Nonabsorbable Polypropylene/Polyethylene Surgical Suture pledget is substantially equivalent to:

- PremiCron Nonabsorable PET Surgical Suture, Aesculap Inc. (K012201)

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 will be offered dyed with the FDA approved colorant [Phthalacyaninato(2-)] copper in accordance with Title 21 CFR, §74.3045. The Optilene suture will be offered in diameters ranging from USP size 10-0 through 0 and with be available in a variety of cut lengths with or without needles attached. The Optilene sutures will also be offered with or without pledgets composed of 100% polytetrafluorothylene (PTFE). The pledgets are also available separately packaged six per pouch.

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.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

As established in this submission, the Aesculap Optilene suture is a synthetic nonabsorbable monofilament surgical suture offered dyed 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.

Please see attached Substantial Equivalence table comparing the Optilene Nonabsorbable Polypropylene/Polyethylene Suture to the predicate devices.

PERFORMANCE DATA

As recommended by the FDA's Class II Special Control Guidance Document for Surgical Sutures, including mechanical testing in accordance to USP 35 and biocompatibility testing in accordance to ISO 10993-1 has been performed to demonstrate that the Optilene Nonabsorbable Suture is substantially equivalent to other predicate devices.

Tests were conducted for diameter, tensile strength, and needle attachment. All specifications were met. Biocompatibility testing within this submission includes the following: Cytotoxicity, Sensitization, Intracutaneous Irritation, Hemolysis, Genotoxicity – Mouse Lymphoma, Mouse Peripheral Blood Micronucleus, Bacterial Reverse Mutation and Muscle Implantation (12-week).

Testing demonstrated that the device is as safe, as effective, and performs as well as the predicate devices.

Additional chemical characterization testing and a biological risk assessment were conducted in order to evaluate the chemical equivalency of the polypropylene/polyethylene raw material. The results of this testing demonstrate that the Optilene Nonabsorbable Suture is substantially equivalent to the predicate devices.

The Optilene Nonabsorbable Suture is blister packed and sterilized by ethylene oxide. Accelerated aging data for the Optilene Nonabsorbable Suture has been generated to support this submission.

	Aesculap, Inc. Optilene Nonabsorbable Suture	Aesculap, Inc. Premilene Nonabsorbable Suture	USS Polypropylene Nonabsorbable Suture	Prolene Polypropylene Nonabsorbable
K#	Pending	K980703	K050947/K010909/K954808	N16374
Indications	Indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.	Indicated for use in all types of general soft tissue approximation and ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.	Indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological surgery.	Indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, and neurological surgery.
Material	95% polypropylene and 5% Polyethylene	Polypropylene	Polypropylene and Polyethylene	Polypropylene
Dyed, Un-dyed	Dyed	Un-dyed and Dyed	Un-dyed and Dyed	Un-dyed and Dyed
Colorant	[Phthalacyaninato(2-)] copper	[Phthalacyaninato(2-)] copper	Copper phthalocyanine, CI 74160	Copper phthalocyanine, CI 74160
Structure	Monofilament	Monofilament	Monofilament	Monofilament
Size	10-0 through 0 (various lengths) with or w/out needles attached with or w/out pledgets attached	11-0 through 2 (various lengths) with or w/out needles attached	10-0 through 2 (various lengths) with or w/out needles attached with or w/out pledgets attached	10-0 through 1 (various lengths) with or w/out needles attached with or w/out pledgets attached
Physical: - Diameter - Length - Needle Attachment - Tensile Strength	All characteristics meet USP Requirements.	All characteristics meet USP Requirements	All characteristics meet USP Requirements, except for diameter.	All characteristics meet USP Requirements
Needles	300-series stainless steel	300 or 455 series stainless steel	300-series stainless steel	300-series stainless steel and tungsten-rhenium
Pledgets	polytetrafluoroethylene	N/A	polytetrafluoroethylene	polytetrafluoroethylene
Packaging	Oval HDPE support with an oval card fold card lid in a tyvek peel pouch and polyester-polyethylenerephatalate film.	Oval HDPE support with an oval card fold card lid in a tyvek peel pouch and polyester-polyethylenerephatalate film.	Foil packaging in a second outer peel-pack with paper and plastic film	Oval HDPE support with an oval card fold card lid in a tyvek peel pouch and polyester-polyethylenerephatalate film.
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Ethylene Oxide (EO)

	Aesculap, Inc. Optilene Nonabsorbable Suture	Aesculap, Inc. PremiCron Nonabsorbable Suture
K#	Pending	K980703
Indications	Indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.	Indicated for use in all types of general soft tissue approximation and ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.
Material	95% polypropylene and 5% Polyethylene	poly(ethylene terephthalate)
Dyed, Un-dyed	Dyed	Un-dyed and Dyed
Colorant	[Phthalacyaninato(2-)] copper	D&C Green no. 6
Structure	Monofilament	Multifilament
Size	10-0 through 0 (various lengths) with or w/out needles attached with or w/out pledgets attached	8-0 through 5 (various lengths) with or w/out needles attached with or w/out pledgets attached
Physical: - Diameter - Length - Needle Attachment - Tensile Strength	All characteristics meet USP Requirements.	All characteristics meet USP Requirements
Needles	300-series stainless steel	300 or 400 series stainless steel
Pledgets	polytetrafluoroethylene	polytetrafluoroethylene
Packaging	Oval HDPE support with an oval card fold card lid in a tyvek peel pouch and polyester-polyethylenerephatalate film.	Oval HDPE support with an oval card fold card lid in a tyvek peel pouch and polyester-polyethylenerephatalate film.
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)

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

July 15, 2014

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

Re: K133890
Trade/Device Name: Aesculap Optilene Nonabsorbable Surgical Suture
Regulation Number: 21 CFR 878.5010
Regulation Name: Nonabsorbable polypropylene surgical suture
Regulatory Class: Class II
Product Code: GAW
Dated: June 11, 2014
Received: June 12, 2014

Dear Mr. Racovsky:

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

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)*
K133890

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Peter L. Hudson -S

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:

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Food and Drug Administration
Office of Chief Information Officer
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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."