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

February 17, 2016

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

Re: K151165
Trade/Device Name: Aesculap Dafilon Nonabsorbable Polyamide Surgical Suture
Regulation Number: 21 CFR 878.5020
Regulation Name: Nonabsorbable Polyamide Surgical Suture
Regulatory Class: Class II
Product Code: GAR
Dated: January 8, 2016
Received: January 11, 2016

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 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)*
K151165

Device Name
Dafilon Nonabsorbable Polyamide Surgical Sutures

Indications for Use *(Describe)*
Dafilon Nonabsorbable Polyamide Surgical Sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and 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)

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)*

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.

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"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."

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

Aesculap Dafilon Nonabsorbable Polyamide Surgical Suture
February 12, 2016

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

510(k): K151165

TRADE NAME: Dafilon Nonabsorbable Polyamide Surgical Suture

COMMON NAME: Nonabsorbable Polyamide Surgical Suture

CLASSIFICATION: Class II

CLASSIFICATION NAME: Suture, Nonabsorbable, Synthetic, Polyamide

REGULATION NUMBER: 878.5020

PRODUCT CODE: GAR

PURPOSE FOR PREMARKET NOTIFICATION

The Dafilon Nonabsorbable Polyamide Surgical Suture described in this submission introduces Phthalocyaninato (2)-Copper as a colorant, two packaging types and extends the available suture length range from 3 cm to 250 cm to the existing product line Dafilon Nonabsorbable Polyamide Surgical Suture K990090.

PREDICATE DEVICE

- Primary Predicate: Dafilon Nonabsorbable Polyamide Surgical Suture (K990090)
- Aesculap Optilene Nonabsorbable Suture (K133890)

DEVICE DESCRIPTION

Dafilon is a nonabsorbable monofilament surgical suture which is supplied sterile. Dafilon is composed of the long-chain aliphatic polymers polyamide 6 and/or 6,6. The Dafilon suture is offered undyed and dyed with FDA approved colorants Logwood extract in accordance with Title 21 CRF, §73.1410 or [Phthalocyaninato(2-)] copper in accordance with Title 21 CFR,

§74.3045. The Dafilon suture will be offered in diameters ranging from USP size 11-0 through 5 and will be available in a variety of cut lengths with or with out needles attached.

INDICATIONS FOR USE

Dafilon Nonabsorbable Polyamide Surgical Sutures are indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neurological procedures.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

As established in this submission, the Aesculap Dafilon suture is a synthetic nonabsorbable monofilament surgical suture offered undyed and 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. The device characteristics comparing the Dafilon Nonabsorbable Polyamide Surgical Suture to the predicate devices are summarized below.

	Aesculap, Inc. Dafilon Nonabsorbable Polyamide Suture	**Aesculap, Inc. Dafilon Nonabsorbable Polyamide Suture**	**Aesculap, Inc. Optilene Nonabsorbable Suture**
K#	K151165	K990090	K133890
Indications	Indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neurological procedures.	Indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.	Indicated for use in all types of general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic, microsurgery and neural tissue.
Material	Polyamide 6 and/or polyamide 6,6	Polyamide 6 and/or polyamide 6,6	95% polypropylene and 5% Polyethylene
Dyed, Un-dyed	Un-dyed and Dyed	Un-dyed and Dyed	Dyed
Colorant	[Phthalocyaninato(2-)] copper or logwood extract	FD&C Blue no. 2 or logwood extract	[Phthalocyaninato(2-)] copper
Structure	Monofilament	Monofilament	Monofilament
Size	11-0 through 5 (various lengths) with or w/out needles attached	11-0 through 6 (various lengths) with or w/out needles attached	10-0 through 0 (various lengths) with or w/out needles attached
Thread length	-3 cm to 250 cm -ligature reels of longer length	-5 cm to 150 cm -ligature reels of longer length	-8cm to 150cm -ligature reels of longer length
Physical: - Diameter - Length - Needle Attachment - Tensile Strength	All characteristics meet USP Requirements.	All characteristics meet USP Requirements	All characteristics meet USP Requirements.

	Aesculap, Inc. Dafilon Nonabsorbable Polyamide Suture	**Aesculap, Inc. Dafilon Nonabsorbable Polyamide Suture**	**Aesculap, Inc. Optilene Nonabsorbable Suture**
K#	K151165	K990090	K133890
Needles	300 or 400 series stainless steel	300 or 400 series stainless steel	300-series stainless steel
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 Coated cardboard support in peel pouch. Medical grade paper and PET/LDPE laminate outer pouch. or PE suture support in a PETG tray sealed with a tyvek lid. Medical grade paper and PET/LDPE laminate outer pouch.	Oval 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.	Oval HDPE support with an oval card fold card lid in a tyvek peel pouch and polyester-polyethylenerephatalate film.
Sterilization	Gamma Irradiation or Ethylene Oxide (EO)	Gamma Irradiation	Ethylene Oxide (EO)

PERFORMANCE DATA

As recommended by the FDA's Class II Special Control Guidance Document for Surgical Sutures, including mechanical testing in accordance to USP 37 and biocompatibility testing in accordance to ISO 10993-1 has been performed to demonstrate that the Dafilon Nonabsorbable Suture is substantially equivalent to other predicate devices.

Tests were conducted for diameter, tensile strength, and needle attachment. All specifications were met. The Dafilon suture is considered an implant device, tissue/bone contact device of permanent duration (>30 days). In accordance with ISO 10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing," Biocompatibility testing within this submission includes the following: Cytotoxicity, Sensitization, Intracutaneous Irritation, Systemic and Muscle Implantation (4-week).

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

Additional chemical characterization testing was conducted in order to evaluate the chemical equivalency of the polyamide raw material. The results of this testing demonstrates that the Dafilon Nonabsorbable Suture is substantially equivalent to the predicate devices.

The Dafilon Nonabsorbable Polyamide Suture is blister packed and sterilized by either gamma Irradiation or Ethylene Oxide. Accelerated aging data for the Dafilon Nonabsorbable Suture has been generated to support this submission.