K122734 page 1/2

DEC 18 2012

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

Aesculap® Novosyn Absorbable Suture
December 5, 2012

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® Novosyn Absorbable Suture

COMMON NAME: Synthetic Polyglycolic Absorbable Suture

CLASSIFICATION NAME: Suture, Absorbable, Synthetic, Polyglycolic Acid

REGULATION NUMBER: 878.4493

PRODUCT CODE: GAM

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Novosyn Absorbable Suture is substantially equivalent to:

- Safil Synthetic Absorbable Surgical Suture, Aesculap Inc. (K980704)
- Coated Vicryl (Polyglactin 910) Suture, Ethicon Inc. (K022269)

DEVICE DESCRIPTION

Novosyn is a synthetic absorbable braided surgical suture which is supplied sterile. Novosyn is composed of a copolymer made from 90% gylcolide and 10% L-lactide (PGLA). The Novosyn suture is coated with 35/65 poly(glycolide-co-L-lactide) and calcium stearate. The Novosyn suture will be offered undyed or dyed with the FDA approved colorant D&C Violet No.2 in accordance with Title 21 CFR, §74.3206. The Novosyn suture will be offered in diameters ranging from USP size 8-0 through 2 and will be available in a variety of cut lengths with or without needles attached.

K122734

INDICATIONS FOR USE

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.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

As established in this submission, the Aesculap Novosyn suture is a synthetic absorbable braided surgical suture offered undyed or 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.

PERFORMANCE DATA

As recommended by the FDA's Class II Special Control Guidance Document for Surgical Sutures, including mechanical testing in accordance to USP 34, 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 Absorable Suture is substantial equivalent to other predicate devices.

Tests were conducted for diameter, tensile strength, and needle attachment. All specifications were met apart from diameter. 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 (12-week).

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Aesculap, Inc.
% Ms. Kathy A. Racosky
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

December 18, 2012

Re: K122734
Trade/Device Name: Aesculap® Novosyn 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: December 05, 2012
Received: December 06, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K122734

Device Name: Aesculap® Novosyn Absorbable Suture

Indications for Use:

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.

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K122734