

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

Aesculap® MonoMax Absorbable Suture
July 13, 2010

JUL 14 2010

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® MonoMax Poly(hydroxybutyrate) Absorbable Suture

COMMON NAME: Poly(hydroxybutyrate) Absorbable Suture

CLASSIFICATION NAME: Absorbable poly(hydroxybutyrate) surgical suture

REGULATION NUMBER: 878.4494

PRODUCT CODE: NWJ

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the MonoMax Absorbable Suture is substantially equivalent to the Tephaflex® Absorbable Suture (K082178/K081099/K052225).

DEVICE DESCRIPTION

The Aesculap® MonoMax Absorbable Sutures are sterile, monofilament, absorbable surgical sutures constructed of poly-4-hydroxybutyrate. The MonoMax sutures will be offered in sizes 2, 1, 0, 2-0, 3-0, 4-0, and 5-0. The sutures will be available in a variety of cut lengths with or without needles attached. The sutures will be available undyed, and dyed with the FDA approved colorant D&C Violet No.2 in accordance with Title 21 CFR, 74.3602.

INDICATIONS FOR USE

MonoMax absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The MonoMax sutures are offered in the same range of sizes as the predicate devices. The material used for the MonoMax sutures is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

Testing was performed in accordance to FDA's Class II Special Control Guidance Document for Surgical Sutures, including mechanical testing in accordance to USP 28, biocompatibility testing in accordance to ISO 10993-1, and animal testing to demonstrate the resorption profile of the device. All specifications were met apart from diameter. Please reference K082178 for performance data, which were collected by Tepha, Inc. for the predicate device, that were used to support the substantial equivalence of the MonoMax suture device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Aesculap® Inc.
% Ms. Kathy A. Rocosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

JUL 14 2010

Re: K100876

Trade/Device Name: Aesculap® MonoMax Absorbable Suture

Regulation Number: 21 CFR 878.4494

Regulation Name: Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology.

Regulatory Class: II

Product Code: NWJ

Dated: June 15, 2010

Received: June 16, 2010

Dear Ms. Rocosky:

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.

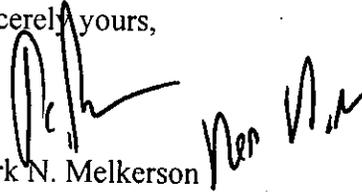
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



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

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: Aesculap® MonoMax Absorbable Suture

Indications for Use:

MonoMax absorbable sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues, microsurgery or ophthalmic surgery.

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)

Daniel Kravitz for MxM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K 100876