NOV 19 2004

K042897

AUTOBAHN Tissue Closure Device and Disposable Cartridge 510(k) Summary of Safety and Effectiveness

Company
Ethicon Endo-Surgery, Inc.
4545 Creek Rd.
Cincinnati, OH 45242

Contact
Elizabeth Miller
Regulatory Affairs Associate I

Date Prepared:
October 19, 2004

Name of Device
Trade Name: AUTOBAHN Tissue Closure Device
AUTOBAHN Disposable Cartridge
Classification Name: Suture, Absorbable, Natural (GAL), Class II, 878.4830

Predicate Device: FASTCLOSE Fascia Closure Device

Device Description: The AUTOBAHN Tissue Closure Device is a non-sterile, reusable device for use with the AUTOBAHN Disposable Cartridge. The AUTOBAHN Disposable Cartridge is a sterile; single-use disposable cartridge containing a standard type needle and standard, absorbable and non-absorbable, suture that is attached to the re-usable AUTOBAHN Tissue Closure Device. The AUTOAHN Tissue Closure Device and Disposable Cartridge are indicated for soft tissue approximation and/ or ligation in general surgical procedures. The needle is contained within the AUTOBAHN Disposable Cartridge before, during, and after the case, aiding in the prevention of suture needle sticks to the surgeons, nurses, and OR staff. The AUTOBAHN tissue Closure Device needle is driven around inside the cartridge in a complete 360° arc. A completed stitch is placed each time the needle and suture are driven across the aperture and through tissue located within the aperture.

Intended Use: AUTOBAHN Tissue Closure Device and Disposable Cartridge is intended for soft tissue approximation and/ or ligation in general surgical procedures.

Technological Characteristics: The technological characteristics of the AUTOBAHN Tissue Closure Device and Disposable Cartridge are identical to those of the predicate device FASTCLOSE Fascia Closure Device K011105, cleared 5/30/01.

Section I

Truthful and Accurate Statement

The Truthful and Accurate Statement, as required by 21 CFR 807.87(k) is provided below.

We, the undersigned, certify that, in our capacity as associates of Ethicon Endo-Surgery, Inc., believe, to the best of our knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact related to a substantial equivalence decision has been omitted.

Elizabeth L Miller

Elizabeth Miller
Regulatory Affairs Associate I

October 19, 2004
Date

Jim Bedi
Lead Design Engineer

October 19, 2004
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Elizabeth Miller
Regulatory Affairs Associate I
Ethicon Endo-Surgery, Inc.
4545 Creek Road
Cincinnati, Ohio 45242

Re: K042897
Trade/Device Name: AUTOBAHN Tissue Closure Device and Disposable Cartridge
Regulation Number: 21 CFR 878.4830
Regulation Name: Absorbable surgical gut suture
Regulatory Class: II
Product Code: GAL
Dated: October 19, 2004
Received: October 20, 2004

Dear Ms. Miller:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K042897

Indications for Use

510(k) Number (if known): K042897

Device Name: AUTOBAHN Tissue Closure Device and Disposable Cartridge

Indications for Use: The AUTOBAHN Tissue Closure Device and Disposable Cartridge is intended for soft tissue approximation and/ or ligation in general surgical procedures.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042897