JUN 12 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

I. GENERAL INFORMATION

A. Submitted By:

J&J Corporate Biomaterials Center, a division of Ethicon
Rt. 22 West, P.O. Box 151
Somerville, NJ 08876-0151

Tel: (908) 218-2041
Fax: (908) 218-3679

Contact Person:

David A. Dalessandro
At address above

B. Device Trade Name: AFB
Common Name: Staple Line Reinforcement Material
Classification Name: Mesh, Surgical, Polymeric

C. Predicate Devices:

Manufacturer	Product Name	510(k) No.
Bio-Vascular, Inc.	Peri-Strips Dry®	K921895 K923657 K940205 K942583 K971048 K992537
W.L. Gore	Seamguard™	K955364 K001789
Ethicon, Inc.	Coated Vicryl II	K915835
Ethicon, Inc.	Monocryl (poliglecaprone 25) suture, dyed	K960653 K964072

D. Device Description:

The AFB (Absorbable Foam Buttress) Reload is a sterile, single patient use device which consists of two components: a cartridge and an anvil carrier. A strip of buttressing material is attached to both the cartridge and anvil carrier. AFB reinforces the staple line in soft tissue while it is simultaneously being cut and stapled. AFB is prepared from a synthetic,

bioabsorbable copolymer similar to that used in synthetic absorbable sutures.

The AFB is integrated into endoscopic and open linear cutting/transecting staplers and reload cartridges. The two product reload cartridge configurations are suitable for the Endopath™ Endoscopic Linear Cutter used for VATS cases and the Linear Cutter used for OPEN cases.

The dimensions of AFB with a 0.03" (0.75 mm) thickness, accommodates the above-cited Ethicon-Endosurgery devices:

Device	Dimensions of AFB (Attached to Staple Cartridge) (inches)	Dimensions of AFB (Attached to Staple Anvil Carrier) (inches)
Endoscopic Linear Cutter 45mm Application	1.83 x 0.34	1.83 x 0.59
Linear Cutter 75 mm Application	3.19 x 0.44	3.30 x 0.63

E. Indications for Use:

AFB is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed.

F. Technological Comparison:

Substantial equivalence for AFB is based upon two separate categories of predicate devices. The first category contains predicate devices that address the intended use, mechanism of use, and application (i.e., two marketed buttress materials, namely Peri-Strips Dry® manufactured by Bio-Vascular, Inc. and Seamguard™ manufactured by W. L. Gore).

The second category of predicate devices addresses the composition of AFB in regard to its biocompatibility, safety data, absorption, and biodegradability (i.e., Coated Vicryl II and Monocryl sutures).

II. TESTING

A. Non-Clinical Testing

Non-clinical testing was conducted on AFB to characterize the product. This testing included polymer composition by NMR, inherent viscosity, foam thickness, pore size, tensile strength, moisture content, residuals, force to fire and tear resistance.

B. Preclinical Testing

Preclinical testing on the copolymer was conducted in multiple species to establish pharmacokinetics, toxicology, biocompatibility, and absorbability. AFB, although bioabsorbed in $\leq$ 120 days, was subjected to a preclinical testing regimen consistent with that for a long-term implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2002

Mr. David A. Dalessandro
Director, Implantable Devices
J & J Corporate Biomaterials Center
A Division of Ethicon
Route 22 West, P.O. Box 151
Somerville, NJ 08876-0151

Re: K014183
Trade/Device Name: AFB
Regulation Number: 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 11, 2002
Received: April 15, 2002

Dear Mr. Dalessandro:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

for Mark N Milhern

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

STATEMENT OF INTENDED USE

510(k) Number (if known): K014183

Device Name: AFB

Sponsor Name: J&J Corporate Biomaterials Center,
a division of Ethicon

Indications for Use:

AFB is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
Over-The-Counter Use ☐

for Mark N Milleson

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

510(k) Number K014183