K040759

Endoscopy
Smith & Nephew, Inc.
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Andover, MA 01810

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VI.510(k) Summary

DuraBraid™ Suture
Date Prepared: March 26, 2004

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc., Endoscopy Division
130 Forbes Blvd.
Mansfield, MA 02048

B. Company Contact

Bill McCallum
Sr. Regulatory Specialist

C. Device Name

Trade Name: DuraBraid Suture
Common Name: Braided Polyester Surgical Suture
Classification Name: Nonabsorbable poly(ethylene terephthalate) surgical suture

D. Predicate Device

The Smith & Nephew DuraBraid Surgical Suture is substantially equivalent in design, materials, function and intended use to the following device in commercial distribution. Surgical Specialties Corporation Polyviolene green and white braided polyester surgical suture line.

E. Description of Device

DuraBraid Suture is a nonabsorbable, sterile, surgical suture comprised of braided polyester. It is supplied in several USP sizes white and green, and is available with and without swaged needles attached.

The DuraBraid suture is classified by the General and Plastic Surgery Devices panel, § 878.5000, nonabsorbable poly(ethylene terephthalate) surgical suture, GAT.

F. Intended Use

The Smith & Nephew DuraBraid Suture is indicated for use in approximation and/or ligation of soft tissues.

G. Comparison of Technological Characteristics

The Smith & Nephew DuraBraid suture has the same technological characteristics and is composed of the material as the predicate device. The range of sizes offered by Smith & Nephew is within the marketed range of predicate sizes.

The DuraBraid Suture material conforms to the following Recognized Consensus Standards:

Item 97: USP 26, Nonabsorbable Surgical Sutures
Item 100: USP 26, <881> Tensile Strength
Item 101: USP 26, <861> Sutures – Diameter
Item 102: USP 26, <871> Sutures Needle Attachment
Item 51: AAMI/ANSI/ISO 10993-1: 1997, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing
Item 76: AAMI/ANSI/ISO 10993-7: (R) 2001, Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals
Item 103: AAMI/ANSI/ISO 11607: 2000, Packaging for Terminally Sterilized Medical Devices
Item 75: AAMI/ANSI/ISO 11137: 1994, Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation Sterilization and ISO 11137: 1995 (Amendment 1:2002)
Item 25: AAMI/ANSI/ISO 11135: 1994 Medical Devices-Validation and Routine Control of Ethylene Oxide Sterilization.

The design of the Smith & Nephew DuraBraid surgical suture is in conformance with the above identified standards. The signed Declaration of Conformance with Consensus Standards is located in section II of this Abbreviated 510(k) submission.

Summary of Features and Technological Characteristics in comparison to the Predicate Device

Attribute	DuraBraid	Polyviolene (predicate)
Suture Material	Braided polyester, nonabsorbable (Ashaway)	Braided polyester, nonabsorbable (Ashaway)
Suture Treatment	Uncoated, and silicone coated (Ashaway)	Uncoated, and silicone coated (Ashaway)
Configuration	With and without needles, tipped	With needles and pledgets
Tipping	Kollidon	Unknown
Dyed	D&C Green No. 6	D&C Green No. 6
Undyed	White	White
Sizes	USP sizes 3-0 through 5, USP	USP sizes 11-0 through 5, USP
Needles	T-13 and T-5, Taper point, ½ Circle	Various Needle Types and lengths
Indications	Indicated for use in approximation and/or ligation of soft tissues.	Indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures
Packaging	Sterile, pouches 12 to a carton	Sterile, pouches 12 to a carton

Bill McCallum
Senior Regulatory Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

Mr. Bill McCallum
Senior Regulatory Specialist
Smith & Nephew, Inc.
Endoscopy Division
150 Minuteman Road
Andover, Massachusetts 01810

Re: K040789
Trade/Device Name: DuraBraid™ Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable polyethylene terephthalate surgical suture
Regulatory Class: II
Product Code: GAT
Dated: March 26, 2004
Received: March 29, 2004

Dear Mr. McCallum:

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.

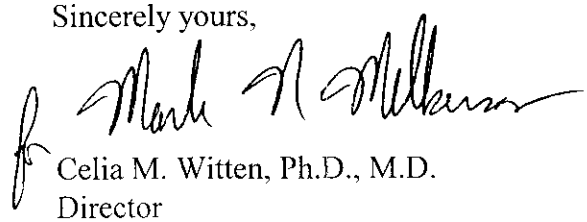
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4659. 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,



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

K040789

INDICATIONS FOR USE STATEMENT

510(K) Number: K 040789

Device Name: DuraBraid ™ Suture

Indications For Use: Smith & Nephew Durabraid™ Suture is indicated for use in approximation and/or ligation of soft tissues.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for

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

510(k) Number K040789