K020480 (P. 1 of 2)

SECTION V

510(k) Summary

MAR 1 2 2002

RBM

Date Prepared: January 25, 2002

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
160 Dascomb Road
Andover, MA 01810
508.261.3658

B. Company Contact

William McCallum
Regulatory Specialist

C. Device Name

Trade Name:	RBM
Common Name:	Suture Retention Device Suture, Nonabsorbable, Polyester
Classification Name:	Suture Retention Device (KGS) Suture, Nonabsorbable, Synthetic, Polyester (GAS)

D. Predicate Device

MR-III previously cleared by K002261.

E. Description of Device

The RBM is a suture retention device manufactured from polyester suture, poly(L-lactide) bar, stainless steel needle and a plastic handle.

D. Intended Use

RBM is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue repair.

The indications for the MR-III are for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair and gastrostomy.

E. Comparison of Technological Characteristics

Both the MR-III and the RBM are intended to be used to fixate soft tissue by anchoring the tissue internally from a single access point and securing the suture by a knot.

William McCallum

Regulatory Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2002

Mr. William McCallum
Regulatory Affairs Specialist
Smith & Nephew, Inc.
Endoscopy Division
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K020480
Trade Name: RBM
Regulation Number: 878.5000
Regulation Name: Synthetic non-absorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: February 11, 2002
Received: February 13, 2002

Dear Mr. McCallum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. Melkerson

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

K020480

510(k) Number : K020480

Device Name : RBM

Indications for Use :

The RBM is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue repair.

The indications for the RBM are for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures such as shoulder stabilization (Bankart Repair), rotator cuff repair, meniscal repair, and gastrostomy.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K020480