3/1/99

K984650

Section 6: 510(k) Summary of Safety and Effectiveness

6.1 Statement	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.
6.2 Submitter	Smith & Nephew, Inc., Endoscopy Division 130 Forbes Blvd. Mansfield, Ma. 02048
6.3 Company Contact	Susan Finneran Clinical/Regulatory Affairs (508) 261-3772
6.4 Device Name	Proprietary Name: Pre-Threaded EndoButton Common Name: Surgical Button Classification Name: Surgical Button
6.5 Predicate Legally Marketed Devices	EndoButton (K933948), EndoButton Tape (K952535), EndoButton Continuous Loop (K980155) Smith and Nephew Endoscopy, Inc. Mansfield, Ma.
6.6 Device Description	The Pre-Threaded EndoButton is a titanium suture retention device packaged sterile, pre-threaded with polyester tape and polyester suture. The construct is used to fixate tendons and ligaments during orthopedic procedures, specifically during ACL reconstructions.

6.7 Intended Use

The Pre-Threaded EndoButton is intended to be used to fixate suture during the repair of tendon and ligament fixation.

6.8 Device Indications

The Pre-Threaded EndoButton is used for fixation of tendons and ligaments during orthopedic reconstructive procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.

6.9 Substantial Equivalence

The Pre-Threaded EndoButton is substantially equivalent to the previously cleared EndoButton (K933948), the previously cleared EndoButton Tape (K952535), and the previously cleared EndoButton Continuous Loop (K980155)

Table of Substantial Equivalence

Product Name	Pre-Threaded EndoButton	EndoButton	EndoButton Tape	EndoButton Continuous Loop
Product Labeling	Sterile (EtO), Single Use	Gamma Irradiation , Single Use	Ethylene Oxide, Single Use	Gamma Irradiation, Single Use
Materials	polyester/titanium	titanium	polyester	polyester/titanium
Intended use	Soft tissue fixation	Soft tissue fixation	For use with the EndoButton in soft tissue fixation	Soft Tissue Fixation
Indications	Tendon and Ligament Fixation	Tendon and Ligament Fixation	Tendon and Ligament Fixation	Tendon and Ligament Fixation
Sterilization Method	Ethylene Oxide	Gamma Irradiation	Ethylene Oxide	Gamma Irradiation

Applicant _____ Date 2/23/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 1999

Ms. Susan Finneran
Clinical/Regulatory Associate
Smith & Nephew Endoscopy
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K984550
Trade Name: Pre-Threaded EndoButton
Regulatory Class: II
Product Code: GAT and MBI
Dated: December 21, 1998
Received: December 22, 1998

Dear Ms. Finneran:

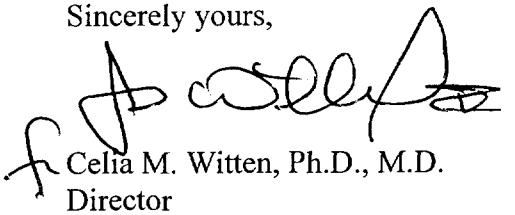
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

K984550

510 (k) Number (If Known):

Device Name: Pre-Threaded EndoButton

Indications For Use:
The Pre-Threaded EndoButton is used for fixation of tendons and ligaments during orthopedic reconstructive procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

or Over-The-Counter Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984550