APR - 1 1998

510(K) SUMMARY

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

The assigned 510(k) number is : K980155

This summary was prepared on January 15, 1998

A. Submitter

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

B. Company Contact

Demetrios Tsakonas
Clinical/Regulatory Specialist

C. Device Name

Trade Name: EndoButton Continuous Loop

Common Name:
- Suture Retention Device; Surgical Button; Retention Bridge
- Polyester Surgical Suture

Classification Name:
- Button, Surgical
- Non absorbable surgical suture (Poly[ethylene terephthalate])

D. Predicate/Legally Marketed Devices

EndoButton & EndoButton Tape
Smith & Nephew, Inc., Endoscopy Division
130 Forbes Boulevard
Mansfield, MA 02048

E. Device Description

The EndoButton Continuous Loop consists of two components. The first is the EndoButton which is made of Titanium 6AL 4V ELI alloy (ASTM F136). Its length is from 12 to 18 mm and its width is from 4 to 6 mm. It is oblong in shape with four holes through which suture is threaded.

The second component is the polyester suture which is preattached to the center holes. The loop span lengths range from 10 to 80 mm and is approximately 5 mm in diameter. The suture portion of the EndoButton Continuous Loop is made of polyester, Poly(ethylene terepthalate). The suture is prepared from fibers of high molecular weight, long chain, linear polyesters having recurrent aromatic rings as an integral component. The suture meets the applicable requirements established by the United States Pharmacopeia (U.S.P.) for non-absorbable surgical suture.

F. Performance

The EndoButton Continuous Loop was tested against the EndoButton with EndoButton Tape to determine if it was equivalent in strength. Tensile strength, Stiffness, Cyclic Fatigue Testing and Residual Tensile Strength were examined. After the testing was completed, it was determined that the EndoButton Continuous Loop is as strong as the currently marketed EndoButton with EndoButton Tape.

G. Intended Use

The EndoButton Continuous Loop is used for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction..

H. Substantial Equivalence

The EndoButton Continuous Loop and the EndoButton & EndoButton Tape have similar designs. Both are used in fixating soft tissue ligaments. The EndoButton components are the same. The suture lengths are similar. The EndoButton tape comes in only one total length 60 cm, where as the suture portion of the EndoButton Continuous Loop will come in a variety of lengths ranging from 10 to 80 mm.

Risks to health have been addressed through the specified materials, processing controls, quality assurance, and compliance to the Medical Device Good Manufacturing Practices regulations.

A summary comparison of the characteristics of the EndoButton Continuous Loop and the substantially equivalent devices is presented in the table below.

	Current Product	Substantially Equivalent Product	Substantially Equivalent Product
Attribute ⇓	EndoButton Continuous Loop	EndoButton K922559	EndoButton Tape K952535
Indication	Fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) Reconstruction.	Soft Tissue Fixation and Repair	Soft tissue approximation specifically for use with EndoButton during orthopedic reconstruction procedures.
Dimensions	EndoButton: width: 4 - 6 mm length: 12 - 18 mm Suture loop span length: 10 - 80 mm	EndoButton: width: 4 - 6 mm length: 12 - 18 mm	EndoButton Tape Total Suture length: 60 cm
Material	EndoButton: Titanium Suture: Polyester	Titanium	Polyester
Sterilization	gamma irradiation	gamma irradiation	ethylene oxide
Labeling	Sterile, Single Use Only	Sterile, Single Use Only	Sterile, Single Use Only

Applicant Demetrios Tzakonas Date 1/15/98

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 1998

Mr. Demetrios Tsakonas
Clinical/Regulatory Specialist
Endoscopy Division
Smith & Nephew, Incorporated
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K980155
Trade Name: EndoButton Continuous Loop
Regulatory Class: II
Product Code: GAT and MBI
Dated: January 15, 1998
Received: January 16, 1998

Dear Mr. Tsakonas:

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

510 (k) Number (If Known): K980155

Device Name: EndoButton Continuous Loop

Indications for Use: The EndoButton Continuous Loop is used for fixation of tendons and ligaments during orthopedic reconstruction 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980155

Prescription Use X or Over-The-Counter Use _____
(Per 21 CFR 801.109)