Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: (978) 749-1000 Toll Free: 1-800-343-8386
Fax: (978) 749-1599

Smith+Nephew

K023417
page 1 of 2

SECTION V
510(k) Summary

NOV 7 2002

SURETAC® III

Date Prepared: October 09, 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. 261.3699

B. Company Contact

Jason Bilobram
Regulatory Specialist

C. Device Name

Trade Name:	SURETAC® III
Common Name:	SURETAC® Fixation Device
Classification Name:	Class II, Smooth or Threaded Metallic bone fixation fastener Product Code JDR (prior classification) Class II, Fastener, Fixation, Biodegradable, Soft Tissue Product Code MAI (current classification)

D. Predicate Devices

SURETAC® Fixation Device (K911837)
SURETAC® Expanded Indication (K931519)
SURETAC® Expanded Indication II (K020948)

K023417
page 2 of 2

E. Description of Device

The SURETAC® III is a bioabsorable fixator utilized for soft tissue to bone approximation.

F. Intended Use

SURETAC III is intended for soft tissue to bone approximation.

The indications for the SURETAC III are rotator cuff repair, repair of recurrent anterior shoulder dislocation and subluxaton, and repair of acute/primary anterior shoulder dislocation and subluxation.

G. Comparison of Technological Characteristics

Both the SURETAC Fixation Device and the SURETAC III are intended for approximation of soft tissue to bone.

Jason Bilobram

Jason Bilobram

Regulatory Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 7 2002

Mr. Jason Bilobram
Regulatory Affairs Specialist
Endoscopy Division
Smith & Nephew, Inc.
160 Dascomb Road
Andover, Massachusetts 01810

Re: K023417
Trade/Device Name: SURETAC® III Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDR
Dated: October 10, 2002
Received: October 11, 2002

Dear Mr. Bilobram:

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,

Miriam C Provost

for 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

510(k) Number : K023417

Device Name: SURETAC® III

Indications for Use :

The SURETAC III is indicated for rotator cuff repair, repair of recurrent anterior shoulder dislocation and subluxaton, and repair of acute/primary anterior shoulder dislocation and subluxation.

(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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023417