# Section 7- 510k Summary

**7.1 Statement**

This 510k summary is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

**7.2 Submitter**

Smith and Nephew, Inc.
Endoscopy Division
160 Dascomb Rd.
Andover, Ma. 01810

**7.3 Company Contact**

Jason Bilobram
Regulatory Affairs Specialist
(508) 261-3699

**7.4 Device Name**

**Proprietary Name:** SURETAC® Expanded Indication II
**Common Name:** SURETAC® Fixation Device
**Classification Name:** Smooth or Threaded Metallic Bone Fixation Fastener (JDR)

**7.5 Predicate Legally Marketed Devices**

- Smith & Nephew, SURETAC® Fixation Device (K911837)
- Smith & Nephew, SURETAC® Expanded Indication (K 931819)

**7.6 Device Description**

The PGA/TMC SureTac is composed of bioresorbable and biocompatible polymers that have been used in various surgical procedures for many years. Polyglycolic Acid (PGA) and Trimethylene carbonate (TMC) copolymer degrades and resorbs *In Vivo* by hydrolysis and are metabolized by the body. In animal studies PGA/TMC, also know as, Maxon have been shown to be biocompatible in both soft tissue and bone tissue.

**7.7 Indications for Use**

The Smith & Nephew SURETAC® Fixation Device is indicated for rotator cuff repair.

**7.8 Substantial Equivalence**

The SURETAC® Fixation Device is substantially equivalent in design, material, packaging materials and method of sterilization to the following currently marketed devices:

- Smith & Nephew, SURETAC® Fixation Device (K911837)
- Smith & Nephew, SURETAC® Expanded Indication (K 931819)

- The only difference between the proposed and predicate devices is the expansion of the patient population to include rotator cuff repair.

**Applicant:** Jason Bilobram **Date:** 03/21/2002

Jason Bilobram
Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 9 2002

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

Re: K020948
Trade/Device Name: SURETAC® Expanded Indications II
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDR
Dated: July 17, 2002
Received: July 18, 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,

for 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): K020948

Device Name: SURETAC® Expanded Indications II

Indications for Use: Indicated for use in Rotator Cuff Repair

(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
and Neurological Devices

510(k) Number K020948

Prescription Use Yes
(Per 21 CFR 801.109)

*OR*

Over-The-Counter Use No