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NOV 0 2 2001

510(k) Summary
Smith & Nephew Phoenix 5.0 Allograft Anchor Kit
Revision Date: September 24, 2001

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

B. Company Contact

Tim Crabtree
Regulatory Affairs Specialist

C. Device Name

Trade Name: Smith & Nephew Phoenix 5.0 Allograft Anchor Kit
Common Name: Soft Tissue Suture Anchor
Classification Name: Unclassified

D. Predicate Devices

Smith & Nephew Preloaded PRC5 5.0 mm Polyacetal Suture Anchor (K982963)
Multitak SS Bone Anchor (K993115)

E. Description of Device

The Smith & Nephew Phoenix 5.0 Allograft Anchor Kit composed of machined cortical bone. The anchor is of a threaded design with two (2) eyelets, to which braided #2 USP suture is attached (one per eyelet). The proximal end of the anchor accepts a disposable driver, which is used as the insertion device. The anchor requires a tapping procedure prior to implantation. Following the implantation of the anchor, the free ends of the suture are used to reattach soft tissue to bone.

F. Intended Use

The Smith & Nephew Phoenix 5.0 Allograft Anchor Kit is intended for use only for the fixation of soft tissue to bone for the following indications:

Shoulder:

1. Bankart lesion repairs
2. SLAP lesion repairs

3. Acromioclavicular separation repairs
4. Rotator cuff tear repairs
5. Capsular shift or capsulolabral reconstructions
6. Biceps tenodesis
7. Deltoid repairs

Foot and Ankle:

1. Hallux valgus repairs
2. Medial or lateral instability repairs/reconstructions
3. Achilles tendon repairs/reconstructions
4. Midfoot reconstructions
5. Metatarsal ligament/tendon repairs/reconstructions

Elbow, Wrist, and Hand:

1. Scapholunate ligament reconstructions
2. Ulnar or radial collateral ligament reconstructions
3. Lateral epicondylitis repair
4. Biceps tendon reattachment

Knee:

1. Extra-capsular repairs:
    a. medial collateral ligament
    b. lateral collateral ligament
    c. posterior oblique ligament
2. Iliotibial band tenodesis
3. Patellar realignment and tendon repairs, including vastus medialis obliquous advancement

G. Comparison of Technological Characteristics

The Smith & Nephew Phoenix 5.0 Allograft Anchor Kit is substantially equivalent in design, function and intended use to the Smith & Nephew PRC5 Polyacetal Anchor. Performance testing has been performed to support substantial equivalance. It is substantially equivalent in its materials and use to the Mutlitak SS Bone Anchor.

Tim Crabtree

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 2 2001

Mr. Tim Crabtree
Regulatory Affairs Specialist
Smith & Nephew, Inc.
160 Dascomb Road
Andover, Massachusetts 01810

Re: K011985
Trade/Device Name: Smith & Nephew Phoenix 5.0 Allograft Anchor Kit
Regulation Number: 21 CFR 888.3040 and 878.5000
Regulation Name: Smooth or threaded metallic bone fixation fastener and nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: MAI, JDW, BAS
Dated: June 19, 2001
Received: June 26, 2001

Dear Mr. Crabtree:

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 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

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510(k) Number : NOV 0 2 2001

Device Name : The Smith & Nephew Phoenix 5.0 Allograft Kit

Indications for Use :

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3. Patellar realignment and tendon repairs, including vastus medialis obliquous advancement

for Mark N Milleman

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

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