FEB 25 2000

K994202 1 OF 3

VI. 510K Summary and Truthful and Accurate Statement

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 : _____

This summary was prepared on December 10, 1999.

A. Submitter

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

B. Company Contact

Nicholas Condakes
Regulatory Affairs Specialist

C. Device Name

Proprietary Name:	Acufex® Spiked Washer System Acufex® Suture Washer System Acufex® Cancellous Screw and Spiked Suture Washer System
Common Name:	Soft Tissue Fixation Screw and Washer
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Product Code:	Screw: HWC Washer: HTN
Regulatory Class:	The Orthopedic Device Panel has classified Screws and Washers as a Class II device (21 CFR § 888.3030).

VI. 510K Summary and Truthful and Accurate Statement

D. Predicate/Legally Marketed Devices

Acufex® Tibial Anchor Screw and Spiked Washer (K961649):
Smith + Nephew Inc., Endoscopy Division
130 FORBES BLVD
MANSFIELD, MA 02048

DePuy OrthoTech Soft Tissue Fixation Washer (K910229)
DePuy OrthoTech, Inc.

700 Orthopaedic Drive
Warsaw, IN 46581

E. Device Description

The Acufex® Washer Systems are used in fixation of soft tissue to bone. The systems include various style polyacetal (with a titanium ring) or titanium washers and titanium screws. The screws are available with a diameter range from 4.5 to 9 mm and 18 to 70 mm in length. Various washers have spikes to engage to bone. Suture spiked washers are designed with spikes for engagement to bone and suture holes to secure suture tendon construct. Also, suture washers are used to secure suture tendon construct to bone.

F. Indications for Use

The Acufex® Washer Systems are used for fixation of soft tissue, such as tendons and ligaments to bone during orthopedic procedures.

VI. 510K Summary and Truthful and Accurate Statement

G. Substantial Equivalence

	Subject Device Acufex® Washer Systems	Predicate Device Acufex® Tibial Anchor Screw & Spiked Washer (K961649)	Predicate Device DePuy OrthoTech Soft Tissue Fixation Washer (K910229)
DESIGN			
Screw Configuration	Cancellous	Cancellous	Cancellous
Screw size	Screw length 18 – 70 mm	Screw length 18 - 30 mm	Screw length 25-65 mm
	Screw diameter 4.5 - 9 mm	Screw diameter 7 – 9 mm	Screw diameter 6.5 mm
Washer size	Outer diameter 13 – 22 mm	Outer diameter 14 – 20 mm	Outer diameter 14 – 20 mm
INDICATIONS FOR USE			
	Soft tissue fixation	Soft tissue fixation	Soft tissue fixation
MATERIALS			
Screw	Titanium	Titanium	Titanium
Washer	Titanium reinforced, Polyacetal polymer Or Titanium	Titanium reinforced, Polyacetal polymer	Titanium
LABELING			
Screw	Sterile, Single Use Only/ Non-Sterile, Single Use	Sterile, Single Use Only/ Non-Sterile, Single Use	Sterile, Single Use Only
Washer	Sterile, Single Use Only / Non-Sterile, Single Use	Sterile, Single Use Only	Sterile, Single Use Only

Applicant Nicholas Conduker Date 12/10/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 25 2000

Mr. Nicholas Condakes
Regulatory Affairs Specialist
SMITH & NEPHEW, INC.
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K994202
Trade Name: Acufex® Washer System
Regulatory Class: II
Product Code: HWC and HTN
Dated: December 10, 1999
Received: December 13, 1999

Dear Mr. Condakes:

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 control provisions of the Act. The general control 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) 594-4659. 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" (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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K994202

Device Name **Acufex® Washer Systems**

Indications For Use:

The Acufex® Washer Systems are indicated for fixation of soft tissue, such as tendons and ligaments to bone in orthopedic procedures.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use_____
(Per 21 CFR §801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994202