SEP 19 1997

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 : K972599

This summary was prepared on July 2, 1997

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:	Acufex® Screw Cannula
Common Name:	Screw and Cannula
Classification Name:	Screw, Fixation, Bone Cannula, Surgical

D. Predicate/Legally Marketed Devices

Arthrex® Sheathed Interference Screw
3050 North Horseshoe Drive
Naples, FL 33942
510(k) #: K915424

E. Device Description

The Acufex Screw Cannula is a cylindrical device that has a distal, screw holding end, and an open back end. The proximal end is shaped to allow for secure grasping of the cannula during insertion. The distal end contains a feature that allows the screw to be held snugly in the cannula. This is accomplished by creating an interference fit between the screw and the cannula walls.

F. Intended Use

The Acufex Screw Cannula is used for fixation of bone-tendon-bone grafts during Anterior or Posterior Cruciate Ligament (ACL/PCL) reconstruction procedures.

G. Substantial Equivalence

The Acufex Screw Cannula is intended for use for fixation of bone tendon grafts during ACL/PCL reconstructions. The Acufex Screw Cannula is similar in design, function, materials and intended use to other devices currently marketed and in commercial distribution, namely the Arthrex® Sheathed Interference Screw.

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 Acufex Screw Cannula and the substantially equivalent device is presented in the table below.

	Current Product	Substantially Equivalent Product
Attribute ⇓	Acufex® Screw Cannula	Arthrex® Sheathed Interference Screw 510K#: K915424
Indication	Bone Tendon Bone Graft Fixation ACL & PCL Reconstruction	Bone Tendon Bone Graft Fixation ACL & PCL Reconstruction
Screw Configuration	Interference	Interference
Screw Size	Outer Length: 20 - 30 mm Diameter: 5.5 - 9 mm	Length 25 - 55 mm Diameter 6 - 9 mm
Screw Material	Titanium	Titanium
Cannula/Sheath	Polypropylene	Polyethylene
Labeling	Sterile, Single Use Only	Sterile, Single Use Only

Applicant Demetrios Isakonas Date 7/11/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

SEP 19 1997

Re: K972599
Trade Name: Acufex® Screw Cannula
Regulatory Class: II
Product Code: HWC
Dated: July 11, 1997
Received: July 14, 1997

Dear Mr. Tsakonas:

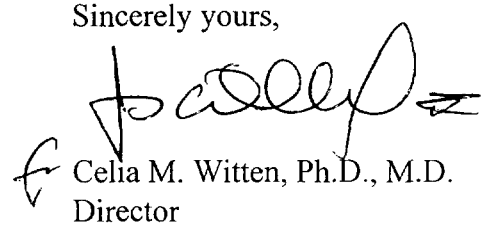
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirements , 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): K972599

Device Name: Acufex Screw Cannula

Indications for Use: The Acufex Screw Cannula is used for fixation of bone-tendon-bone grafts during Anterior or Posterior Cruciate Ligament (ACL/PCL) reconstruction procedures.

(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 K972599

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