

MAY 20 1998

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 : K980841

This summary was prepared on March 2, 1998

A. Submitter

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

B. Company Contact

Demetrios Tsakonas
Clinical/Regulatory Specialist

C. Device Name

Proprietary Name: RCI Fixation Screws
Common Name: Screw, Fixation, Bone, Orthopedics
Classification Name: Screw: 87HWC
Classification: The Orthopedics Device Panel has classified Screw, Surgical as a Class II device. (21 CFR § 878.4930)

D. Predicate/Legally Marketed Devices

Arthrex Extra Long Screw (K915424):
Arthrex
3050 NORTH HORSESHOE DRIVE
SUITE 200
NAPLES, FL 33942

RCI Screw (K945687):
Smith & Nephew Inc., Donjoy Division
2777 LOKER AVE. WEST
CARLSBAD, CA 92008

E. Device Description

RCI Fixation Screws are rounded head interference screws which include diameters from 7 to 9 mm and a range of lengths from 25 mm to 50 mm. To allow for maximum amount of thread engagement, the thread profile is constant throughout the entire length of the screw. Except for direction of the threads, the Reverse Thread RCI screw is identical to the current RCI screw.

F. Performance

Bench Testing

RCI Fixation screws have been tested in the laboratory and found to have suitable fixation strength for use as interference screws.

G. Intended Use

RCI Fixation Screws are used for interference fixation of Bone-Tunnel-Bone or Hamstring grafts in anterior or posterior cruciate ligament reconstruction.

H. Substantial Equivalence

Attribute ↓	Current Product	Substantially Equivalent Product	Substantially Equivalent Product
Indication	RCI Fixation Screws Graft Fixation for ACL/PCL Reconstruction	RCI Screw Graft Fixation for ACL Reconstruction	Arthrex Extra Long Screw Graft Fixation for ACL/PCL Reconstruction
Dimensions	Length: .985" - 1.97" Major Diameter: .276" - .355"	Length: .985" Major Diameter: .276" - .355"	Length: 1.18" - 1.97" Major Diameter: .315" - .355"
Material	Titanium	Titanium	Titanium
Sterilization	Gamma Irradiation	Gamma Irradiation	NA
Labeling	Sterile/Non-Sterile	Sterile/Non-Sterile	NA

Applicant *Demetrios Sakonaris* Date *3/2/98*



MAY 20 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K980841
Trade Name: Rounded Cannulated Inside-out (RCI)
Fixation Screws
Regulatory Class: II
Product Code: HWC
Dated: March 2, 1998
Received: March 4, 1998

Dear Mr. Tsakonas:

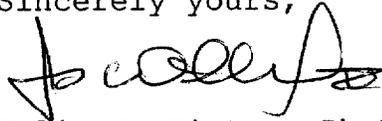
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 pre-market 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



f. 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): K980841

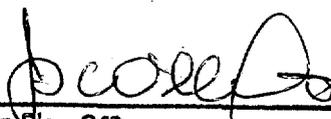
Device Name: RCI Fixation Screws

Indications for Use:

RCI Fixation Screws are used for interference fixation of Bone-Tunnel-Bone or Hamstring grafts in anterior or posterior cruciate ligament reconstruction.

(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 K980841

Prescription Use +
(Per 21 CFR 801.109)

or Over-The-Counter Use _____