

NOV 18 1999

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.

1 of 3

The assigned 510(k) number is : K99294K

This summary was prepared on August 27, 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: 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 § 888.3040)

D. Predicate/Legally Marketed Devices

RCI Fixation Screw (K980841):
Smith + Nephew Inc., Endoscopy
Division
130 FORBES BLVD
MANSFIELD, MA 02048

243
K992945

E. Device Description

RCI Fixation Screws are rounded head interference screws, which include diameters from 6 to 12 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 Fixation 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-Tendon-Bone or soft tissue grafts in anterior or posterior cruciate ligament reconstruction.

K952945

3/3

H. Substantial Equivalence

	Current Product	Substantially Equivalent Product
<u>Attribute</u> ↓	<u>RCI Fixation Screws</u>	<u>RCI Fixation Screws</u> K980841
Indication	Graft Fixation for ACL/PCL Reconstruction	Graft Fixation for ACL/PCL Reconstruction
Dimensions	Length: .985" - 1.97"	Length: .985" - 1.97"
	Major Diameter: .236" - .474"	Major Diameter: .276" - .355"
Material	Titanium	Titanium
Sterilization	Gamma Irradiation	Gamma Irradiation
Labeling	Sterile/Non-Sterile	Sterile/Non-Sterile

Applicant Nicholas Conditakes Date 8/31/99



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 18 1999

Mr. Nicholas Condakes
Regulatory Affairs Specialist
Smith & Nephew, Inc.
130 Forbes Boulevard
Mansfield, Massachusetts 02048

Re: K992945
Trade Name: RCI Fixation Screws
Regulatory Class: II
Product Code: HWC
Dated: August 31, 1999
Received: September 1, 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 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 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.

Page 2 - Mr. Nicholas Condakes

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,



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): K 992945

Device Name: RCI Fixation Screws

Indications for Use:

RCI Fixation Screws are used for interference fixation of Bone-Tendon-Bone or soft tissue 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)

Russell J. Ryan

JRP (Division Sign-Off)
Division of General Restorative Devices

510(k) Number K 992945

Prescription Use *Y*
(Per 21 CFR 801.109)

or Over-The-Counter Use *N*