

JAN 12 2000

10F3

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 : K992396

This summary was prepared on July 16, 1999

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: BioRCI Screw
Common Name: Screw, Fixation, Bone, Orthopedics
Classification Name: Screw: 87HWC

D. Predicate/Legally Marketed Devices

RCI Fixation Screws
Smith & Nephew, Inc. (K980841, 5/20/98)
Endoscopy Division
130 Forbes Boulevard
Mansfield, MA 02048

Bioabsorbable Interference Screw
Smith & Nephew, Inc (K984320, 1/20/99)
Endoscopy Division
130 Forbes Boulevard
Mansfield, MA 02048

E. Device Description

The BioRCI Screw is a screw that has a range of diameters from 7 to 10 mm and a length that ranges from 25 mm to 35 mm. The RCI Fixation Interference Screw is provided in a range of diameters from 7 to 9 mm and a range of lengths from 25 to 50 mm. The Bioabsorbable Interference Screw is provided in a range of diameters from 7 to 9 mm and a length that ranges from 20 mm to 30 mm. The material of construction for both the BioRCI and the Bioabsorbable Interference screws is polylactic acid.

F. Performance

The BioRCI Screw has been tested against the RCI Fixation Screw. Both screws had results that are recorded in the test results located in attachment one.

G. Intended Use

The BioRCI Screw has the same intended use as both the RCI Fixation Screw and the Smith & Nephew Bioabsorbable Interference screws. The RCI Fixation screw is used for fixation of bone-tendon-bone grafts or soft-tissue grafts during Anterior/Posterior Cruciate Ligament (ACL/PCL) reconstruction. The Smith & Nephew Bioabsorbable Interference is used for fixation of bone-tendon-bone grafts or soft-tissue grafts during Anterior/Posterior Cruciate Ligament (ACL/PCL) reconstruction.

H. Substantial Equivalence

The BioRCI Screw, RCI Fixation Screw, and the Bioabsorbable Interference Screw have similar designs. These screws are used in fixating grafts to bone. The material for the Bioabsorbable Interference Screws and the BioRCI screws are the same and the screws have similar dimensions.

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 BioRCI Screw and the substantially equivalent devices is presented in the table below.

Attribute ↓	Current Product BioRCI Screw	Substantially Equivalent Product RCI Fixation Screw	Substantially Equivalent Product Smith & Nephew Bioabsorbable Interference Screw
Indication	Bone-Tendon-Bone or Soft Tissue Graft Fixation for ACL/PCL Reconstruction	Bone-Tendon-Bone or Soft Tissue Graft Fixation for ACL/PCL Reconstruction	Bone-Tendon-Bone or Soft Tissue Graft Fixation for ACL/PCL Reconstruction
Dimensions	Diameter: 7 - 10 mm Length: 25 - 35 mm	Diameter: 7 - 9 mm Length: 25 - 50 mm	Diameter: 7 - 9 mm Length: 20 - 30 mm
Material	PLA	PLA	PLA
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Labeling	Sterile, Single Use Only	Sterile, Single Use Only	Sterile, Single Use Only

Applicant Demetrios Loukonou Date 7/16/99



JAN 12 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992396
Trade Name: BioRCI Screw
Regulatory Class: II
Product Code: HWC
Dated: October 19, 1999
Received: October 20, 1999

Dear Mr. Tsakonas:

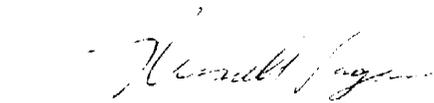
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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,



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): K992396

Device Name: BioRCI Screw

Intended Use:

The BioRCI Screw is used for fixation of bone-tendon-bone or soft tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.

Indications:

- The BioRCI Screw is used for fixation of bone-tendon-bone or soft-tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Sign-Off
of General Restorative Devices
510(k) Number K992396

Prescription Use X
(Per 21 CFR 801.109)

or Over-The-Counter Use _____