

OCT 18 2012

510(k) Summary

Prepared: 19-June-2012
Updated: 17-October-2012

| Submitter Information | Contact Information |
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| Smith & Nephew, Inc., Endoscopy Division 150 Minuteman Road Andover, MA 01810 | Karin Desjardins Senior Regulatory Affairs Specialist Phone: (508) 261-4035 Fax: (508) 261-3620 |

| Device Name: trade, common or proprietary and classification name | |
|---|--|
| Proprietary name | ULTRA FAST-FIX Meniscal Repair System ULTRA FAST-FIX AB Meniscal Repair System FAST-FIX 360 Meniscal Repair System |
| Common Name | Suture retention device |
| Classification Name | Suture, Nonabsorbable, Synthetic, Polyethylene |

Legally Marketed Predicate Devices

The Smith & Nephew ULTRA FAST-FIX, ULTRA FAST-FIX AB, and FAST-FIX 360 Meniscal Repair Systems are substantially equivalent in intended use and Fundamental Scientific Technology to the following legally marketed devices in commercial distribution:

- K041216** *ULTRABRAID Suture*
(cleared June 7, 2004)
- K072332** *ULTRA FAST-FIX / ULTRA FAST-FIX AB Meniscal Repair Systems*
(cleared September 18, 2007)
- K092508** *FAST-FIX 360 Meniscal Repair System*
(cleared January 28, 2010)

Device Description

The Smith & Nephew ULTRA FAST-FIX, ULTRA FAST-FIX AB, and FAST-FIX 360 Meniscal Repair Systems are all-inside meniscal repair devices. Each device includes two polymer implants, pre-tied with non-absorbable suture pre-loaded into a stainless steel needle delivery system with an adjustable length depth penetration limiter. Product variants are offered with either a straight, curved or reverse curved delivery needle, and are provided sterile for single use only.

Intended Use

The Smith & Nephew ULTRA FAST-FIX, ULTRA FAST-FIX AB, and FAST-FIX 360 meniscal repair systems are intended for use as suture retention devices to facilitate percutaneous or endoscopic soft tissue procedures. The ULTRA FAST-FIX, ULTRA FAST-FIX AB, AND FAST FIX 360 are indicated for use in meniscal repairs and allograft transplant procedures. The ULTRA FAST-FIX, ULTRA FAST-FIX AB AND FAST-FIX 360 devices are intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

Technological Characteristics

The Smith & Nephew ULTRA FAST-FIX, ULTRA FAST-FIX AB, and FAST-FIX 360 Meniscal Repair Systems are substantially equivalent in design and fundamental scientific technology to the defined predicate devices and raise no new issues of safety and efficacy.

Performance Data

Clinical literature has demonstrated equivalence between techniques for meniscal repair and meniscal reconstruction procedures such as meniscal allograft transplantation. Cyclic load and ultimate tensile strength performance testing demonstrate that the fixation properties of the Smith & Nephew ULTRA FAST-FIX, ULTRA FAST-FIX AB, and FAST-FIX 360 Meniscal Repair Systems are substantially equivalent to legally marketed predicate device.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew, Incorporated
% Ms. Karin Desjardins
Senior Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

OCT 18 2012

Re: K121861

Trade/Device Name: ULTRA FAST-FIX Meniscal Repair System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: Class II
Product Code: GAT
Dated: September 21, 2012
Received: September 24, 2012

Dear Ms. Desjardins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121861

Device Name: ULTRA FAST-FIX Meniscal Repair System
 ULTRA FAST-FIX AB Meniscal Repair System
 FAST-FIX 360 Meniscal Repair System

Indications for Use:

The ULTRA FAST-FIX Meniscal Repair System is intended for use as suture retention devices to facilitate percutaneous or endoscopic soft tissue procedures. The ULTRA FAST-FIX System is indicated for use in meniscal repairs and allograft transplant procedures. The ULTRA FAST-FIX System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

The ULTRA FAST-FIX AB Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures. The ULTRA FAST-FIX AB System is indicated for use in meniscal repairs and allograft transplant procedures. The ULTRA FAST-FIX AB System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

The FAST-FIX 360 Meniscal Repair System is intended for use as a suture retention device to facilitate percutaneous or endoscopic soft tissue procedures. The FAST-FIX 360 System is indicated for use in meniscal repairs and allograft transplant procedures. The FAST-FIX 360 System is intended to be used for anchoring the allograft to the meniscal rim during allograft transplant procedures.

Prescription Use X

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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