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Summary of Safety and Effectiveness for the Ortheon Medical Teno Fix™ Tendon Repair Device

MAY 15 2003

Submitted by

Ortheon Medical, LLC
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Identification of a Legally Marketed Predicate Device

The Teno Fix™ tendon repair system is substantially equivalent to the Surgical Stainless Steel Sutures manufactured and marketed by Ethicon Incorporated, a Johnson & Johnson Company pursuant to K931271, as well as to the Surgical Stainless Steel Sutures manufactured by Peters Pharmaceutical Laboratory and marketed in the USA by CardioThoracic Systems, Inc., under the Acier brand name pursuant to K991073. The Teno Fix™ tendon repair system is also substantially equivalent to Prolene sutures, which are also manufactured and marketed by Ethicon Incorporated, a Johnson & Johnson Company, pursuant to reclassification as Class II devices on May 31, 1991.

General Description

The Teno Fix™ Tendon Repair System is delivered sterile. It consists of the implantable stainless steel components, implantation accessories, and installation instruments. The implantable components of the device include the anchors, stop beads, and suture. The stainless steel suture is shipped pre-assembled with a crimped stop bead and tapered needle.

The Teno Fix™ Tendon Repair System is supplied with two preloaded, single-use disposable installation instruments for implantation of the Teno Fix™ anchors. A crimping instrument is supplied to crimp the stop bead to the stainless steel core suture thus controlling the overall length of the implanted device.

Intended Use

The Ortheon Medical Teno Fix™ tendon repair system is indicated for the repair of severed or lacerated digital flexor tendons.

Summary of Technological Characteristics

Eleven (11) technological characteristics of the Teno Fix™ were compared to the predicate device and were found to be similar.

Summary of Performance Data

The Teno Fix™ meets the requirements of the following recognized consensus standards.

ASTM F899 – 95, Standard Specification for Stainless Steel Billet, Bar and Wire for Surgical Instruments

ASTM F138 – 00, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)

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[previously titled ASTM F138-92, Standard Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality)]

Sterilization of health care products—Requirements for validation and routine control—Radiation sterilization, *ANSI/AAMI/ISO 11137—1994,* Approved 25 May 1994 by Association for the Advancement of Medical Instrumentation, Approved 11 July 1994 by American National Standards Institute, Inc.

Comparative bench testing has established substantial equivalence to the predicate devices. Furthermore, the device has similar technological characteristics to the predicate devices.

Comparative testing in canines shows substantial equivalence to the predicate devices, demonstrating the biocompatibility of the materials, stability of the implant within the tendon, and the ability of the product to improve healing of the injury over the predicate devices by reducing the gap between severed ends of the tendon.

Results of a comparative clinical study in humans shows the Teno Fix™ Tendon Repair System performs as well or better than the predicate devices, and that it is safe and effective.

The Teno Fix™ Tendon Repair System:

- meets the requirements of the stated standards;
- embodies technological characteristics essentially identical to those of the predicate devices;
- has been shown through clinical study that it performs as well or better than the predicate devices;
- has been shown through clinical study it is safe and effective; and
- has been designed and developed utilizing design control methods in compliance with 21CFR820.

The Teno Fix™ is manufactured per specifications and good manufacturing practices which ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2003

Ortheon Medical, LLC
c/o Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K023594
Trade/Device Name: Teno Fix™ Tendon Repair System
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: March 5, 2003
Received: March 5, 2003

Dear Mr. Kahan:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), 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 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K023594

Device Name Teno Fix™ Tendon Repair System

Indications for Use:

The Ortheon Medical Teno Fix™ Tendon Repair System is intended for the repair of severed or lacerated digital flexor tendons.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023594

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96