510(k) Summary

DePuy never stop moving

MAY 2 1 2013

PRODUCT: HEALIX ADVANCE™ KNOTLESS PEEK ANCHOR
SUBMISSION DATE: FEBRUARY 27, 2013
SUBMISSION TYPE: TRADITIONAL

K130539

SECTION 1

Traditional 510(k) REQUIRED INFORMATION

DEVICE NAME

COMMON NAME:	Suture Anchor
TRADE NAME/PROPRIETARY NAME:	Healix Advance™ Knotless PEEK Anchor (4.75mm) Healix Advance™ Knotless PEEK Anchor (5.5mm)

ADDRESS AND REGISTRATION NUMBER

MANUFACTURER	**DePuy Mitek, Inc.** a Johnson & Johnson company 325 Paramount Drive Raynham, MA 02767 **Owner/Operator #:** 1221934 **FDA Registration #:** 1221934	**Medos SARL** Puits Godet 20 CH 2000 Neuchâtel Switzerland **Owner/Operator #:** 9050053 **FDA Registration #:** 3003702646
STERILIZATION SITE	**Sterigenics Belgium Petit-Rechain S.A.** Zoning Industriel de Petit-Rechain Avenue du Parc, 29 B-4800 Verviers, Belgium **Owner/Operator #:** 9065481 **FDA Registration #:** 3003898115	**Medistri SA** Rte de L'Industrie 96- 1564 Domdidier, Switzerland **FDA Registration #:** 3006946276

DEVICE CLASSIFICATION

Fastener, Fixation, Nondegradable, Soft Tissue, classified as a Class II, product code MBI, regulated under 21 CFR 888.3040.

FDA PRODUCT CODE:	MBI
COMMON CLASSIFICATION NAME:	Fastener, Fixation, Nondegradable, Soft Tissue

CONSENSUS STANDARDS AND GUIDANCE DOCUMENTS

The following FDA Recognized Consensus Standards were used in preparing this 510(k) Premarket Notification:

- ASTM F2026:2008 Standard Specification for PEEK Polymers for Surgical Implant Applications (Orthopedics)
- ISO 10993-1:2009 Biological Evaluation of Medical Devices
- ISO 10993-7:2008 Ethylene Oxide Sterilization Residuals
- ISO 11135-1:2007 Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization
- ISO 14630:2009 Non-active Surgical Implants - General Requirements
- ISO 14971:2012 Medical devices – Application of Risk Management to Medical Devices

PREDICATE DEVICE INFORMATION

PREDICATE DEVICES

- K112249 Healix Knotless™ BR Anchor
- K122123 INTRAFIX® PEEK Tapered Screw
- K061863 Arthrex PushLock PEEK Anchors

K130539

SECTION 1

Traditional Required Information

REASON FOR PREMARKET NOTIFICATION

The purpose of this 510(k) Notification is to outline the following changes: addition of a new size anchor (5.5mm), addition of PEEK (polyetheretherketone) material. For ease of use purposes, the following minor changes were made: removal of the anchor window feature, removal of the ramp feature, modification to the driver handle and threader tab and inclusion of a driver collar on the shaft. This 510(k) Notification will demonstrate the substantial equivalency of the proposed Healix Advance™ Knotless PEEK Anchors used for shoulder fixation of soft tissue to bone in the shoulder against the predicate DePuy Mitek's Healix Knotless™ BR Anchor and Arthrex PushLock PEEK Anchors.

To qualify the proposed Healix Advance™ Knotless PEEK Anchors, various device performance characteristics were tested and evaluated by DePuy Mitek and were found to be substantially equivalent to those of the predicate DePuy Mitek's Healix Knotless™ BR Anchors (K112249) and Arthrex PushLock PEEK Anchors (K061863). The proposed Healix Advance™ Knotless Anchor and the predicate DePuy Mitek's INTRAFIX® PEEK Tapered Screw (K122123) are manufactured using the same PEEK (Polyetheretherketone) material.

Results of performance and safety testing have demonstrated that the proposed devices are substantially equivalent to the predicate devices. Based on the indications for use, technological characteristics, and comparison to predicate devices, the proposed Healix Advance™ Knotless PEEK Anchors have shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 21, 2013

Depuy Mitek Incorporated, a Johnson & Johnson Company
% Ms. Julie Vafides
Regulatory Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K130539
Trade/Device Name: Healix Advance™ Knotless PEEK Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 21, 2013
Received: March 22, 2013

Dear Ms. Vafides:

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 contact 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. 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,

For Erin D. Keith

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

Enclosure

K130539

ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): _____

Device Names: Healix Advance™ Knotless PEEK Anchor

Indications for Use: The Healix Advance™ Knotless Anchors are indicated for use in the following procedures for reattachment of soft tissue to bone:

Shoulder
- Rotator Cuff
- Biceps Tenodesis

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 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)
Page 1 of 1

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices