DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 19, 2016

Medos International SARL
% Kristine Christo
Director, Regulatory Affairs
DePuy Mitek, Inc. a Johnson & Johnson Company
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K160804
Trade/Device Name: INTRAFIX™ Advance Tibial Fastener System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: June 13, 2016
Received: June 14, 2016

Dear Ms. Christo:

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 Parts 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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160804

Device Name
INTRAFIX™ Advance Tibial Fastener System

Indications for Use *(Describe)*
The DePuy Mitek INTRAFIX™ Advance Tibial Sheath and Screw System is indicated for fixation of tissue including ligament, or tendon to bone during cruciate ligament reconstruction.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 2 - 510(k) SUMMARY

INTRAFIX™ Advance Tibial Fastener System

Submitter's Name and Address

Medos International SARL
Chemin-Blanc 38, Le Locle Neuchatel
CH 2400, Switzerland
Date Prepared: March 21, 2016

Contact Person

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Name of Medical Device

Proprietary Name: INTRAFIX™ Advance Tibial Fastener System

Classification Name:
a) Single/multiple component metallic bone fixation appliances and accessories
b) Smooth or threaded metallic bone fixation fasteners

Common Name: Fastener, fixation, soft tissue

Substantial Equivalence

The INTRAFIX™ Advance Tibial Fastener System is substantially equivalent to:

- K123362 MILAGRO® ADVANCE Interference Screw

Reference devices:

- K130539 Healix Advance™ Knotless PEEK Anchor
- K102443 Intrafix Tibial Sheath

Device Classification

INTRAFIX™ Advance BR Screw and Sheath:

- Single/multiple component metallic bone fixation appliances and accessories, classified as Class II, product code MAI, regulated under 21 CFR 888.3030.

INTRAFIX™ Advance PEEK Screw and INTRAFIX™ Advance PP Sheath:

- Smooth or threaded metallic bone fixation fastener, classified as Class II, product code MBI, regulated under 21 CFR 888.3040.

Device Description	The INTRAFIX™ Advance Tibial Fastener System is an implant system used for fixation of tissue including ligament, or tendon to bone during cruciate ligament reconstruction. The INTRAFIX™ Advance Sheaths are available in absorbable BR and non-absorbable Polypropylene materials. The INTRAFIX™ Advance Screws are available in absorbable BR and non-absorbable PEEK materials. The INTRAFIX™ Advance Tibial Sheaths and Screws are supplied sterile ready to use.
Technological Characteristics	The proposed INTRAFIX™ Advance Sheaths and Screws are similar to the predicate MILAGRO® ADVANCE Interference Screw (K123362) in that they share the same intended for use, BR material, screw design, sterilization method, and shelf life. The proposed INTRAFIX™ Advance Screws are similar to the Healix Advance™ Knotless PEEK Anchor (K130539) in that they share the same PEEK material. The proposed INTRAFIX™ Advance Sheaths are similar to the Intrafix Tibial Sheath (K102443) as they share the same Polypropylene material and have a similar design and function.
Indications for Use	The DePuy Mitek INTRAFIX™ ADVANCE Tibial Sheath and Screw System is indicated for fixation of tissue including ligament, or tendon to bone during cruciate ligament reconstruction.
Non clinical Testing	Verification activities were performed on the implant and / or its predicate. Testing assessments include pull out testing, and insertion / failure torque.
Safety and Performance	Results of performance testing have demonstrated that the proposed devices are suitable for their intended use. The proposed device also met requirement of bacterial endotoxin testing. Based on similarities in the indications for use, technological characteristics, and performance in comparison to the predicate devices, the proposed INTRAFIX™ Advance Tibial Fastener System has shown to be substantially equivalent to the predicate device under the Federal Food, Drug and Cosmetic Act.