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510(k) Summary

iBalance Medical, Inc.'s AKR_{FX} Medial Opening Wedge Tibial System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

iBalance Medical, Inc.
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OCT 2 7 2009

Contact Person: Kelly Ammann

Date Prepared: August 4, 2009

Name of Device and Name: AKR_{FX} Medial Opening Wedge Tibial System

Common or Usual Name: Opening Wedge Osteotomy device

Classification Name: Bone fixation appliances and accessories

Predicate Devices

Arthrex, Inc.'s Titanium Opening Wedge Osteotomy System (K032187)
Spine Wave, Inc.'s Wafer System (K033303)
Synthes Spiked Washer (K011583)
Cayenne AperFix Interference Screw (K073426)
Cayenne AperFix Implant (K083607)

Intended Use / Indications for Use

The iBalance AKR_{FX} Medial Opening Wedge Tibial System includes instrumentation, implant, and fixation and is used to provide fixation following Proximal Tibial opening wedge osteotomies. It is intended to be used with adequate post-operative immobilization.

Technological Characteristics

The iBalance AKR_{FX} Medial Opening Wedge Tibial System is comprised of an instrumentation set (AKR_{FX} Medial Instrumentation), a PEEK wedge-like implant (the iFX® Medial PEEK Implant) and PEEK fixation (the iFX® Medial PEEK Cancellous and Cortical Anchors). The system enables surgeons to perform a high tibial opening wedge osteotomy with fixation.

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The iFX® Medial PEEK Implant is provided in three general sizes; Small (SM), Medium (MD), and Large (LG). Two configurations of implant and anchors exist. The implant and anchors work as a single construct to fixate and support the opening wedge at its corrective angle.

Performance Data

Biomaterials in the AKR_{FX} Medial Opening Wedge Tibial System meet standard ISO 10993-1 standard for biocompatibility or ASTM F 899 for stainless steel. Performance testing according to ASTM F 2077 compared physical properties of the iBalance AKR_{FX} System to the Arthex System predicate device. In addition, cadaver studies demonstrated the performance of the AKR_{FX} Instrumentation enables the proper placement of the iFX implant and anchors. Lastly, the company's clinical safety study shows that the differences in the iFX® Medial PEEK Implant System do not raise new safety issues and healing of the osteotomy is not adversely affected by differences in device design as compared to the predicates.

In all instances, the iBalance AKR_{FX} Medial Opening Wedge Tibial System functioned as intended and testing results observed were as expected.

Substantial Equivalence

The iBalance AKR_{FX} Medial Opening Wedge Tibial System is as safe and effective as the identified predicate devices. The iBalance AKR_{FX} Medial Opening Wedge Tibial System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the iBalance AKR_{FX} Medial Opening Wedge Tibial System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the iBalance AKR_{FX} Medial Opening Wedge Tibial System is as safe and effective as the identified predicate devices. Thus, the iBalance AKR_{FX} Medial Opening Wedge Tibial System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

iBalance Medical, Inc.
% Hogan & Hartson LLP
% Ms. Janice M. Hogan
1835 Market Street, 29th Floor
Philadelphia, PA 19103

OCT 2 7 2009

Re: K092381
Trade/Device Name: iBalance AKR_{FX} Medial Opening Wedge Tibial System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: August 4, 2009
Received: August 5, 2009

Dear Ms. Hogan:

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 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/cdrh/comp/ 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K092381

Indications for Use

510(k) Number (if known):

Device Name: **iBalance® AKR_{FX} Medial Opening Wedge Tibial System**

Indications for Use:

"The iBalance AKR_{FX} Medial Opening Wedge Tibial System includes instrumentation, implant, and fixation and is used to provide fixation following Proximal Tibial opening wedge osteotomies.

It is intended to be used with adequate post-operative immobilization."

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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