510(k) SUMMARY

DEC 1 4 2012

AOI Medical, Inc.'s Ascendx™ VCF Repair System

Submitter

AOI Medical, Inc.
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Winter Park FL 32792

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Contact Person: Julian Mackenzie, President and CEO

Date Prepared: July 1, 2011

Name of Device

Ascendx™ VCF Repair System

Classification Name

Arthroscope

Predicate Devices

Kyphon, Inc.'s Kyphx Inflatable Bone Tamps

Intended Use / Indications for Use

The Ascendx™ VCF Repair System is indicated for the treatment of painful pathological fractures of the vertebral body that may result from osteoporosis. It is intended to be used in combination with Ascendx™ Cement.

Technological Characteristics

The Ascendx™ VCF Repair System consists of the Ascendx™ Acu-Cut Cutting Instrument, Ascendx™ RDX Repair Device, and Ascendx™ Inflation Syringe.

The Ascendx™ System is packaged with a previously cleared bone cement (Ascendx™ Cement, manufactured by TECRES S.p.A, K042415), as well as several class I tools, including manual orthopedic surgical instruments and cement mixing and dispensing tools.

Performance Data

Comprehensive bench and clinical testing of the Ascendx™ System was conducted. The testing demonstrated that the System conforms to its design specifications. The testing also demonstrated the Ascendx™ VCF Repair System's ability to mechanically withstand insertion and deployment within a vertebral body. In all instances, the Ascendx™ VCF Repair System functioned as intended.

Nonclincial tests performed included biocompatibility testing in accordance with ISO 10993, sterilization validation, shelf life testing, and the following performance testing: Compressive strength and stiffness testing; maximum balloon inflation pressure testing; balloon inflation pressure testing post-sterilization; maximum balloon inflation pressure testing; balloon force comparison testing; balloon insertion and withdrawal force testing; balloon removal force post-cement insertion testing; balloon assembly bond strength testing; balloon fatigue testing; balloon physical characteristics testing; tentacle pressure testing; tensile testing; flexural stiffness testing; radiopacity testing of marker bands; bond and pressure strength testing; cutting torque testing; weld strength testing; post-repair bone cement porosity testing; bone cement curing properties testing; and bone cement mixing testing. All bench testing confirmed that the product met the necessary specifications for its intended use.

In addition to the bench testing listed above, biocompatibility of the device has been confirmed in accordance with ISO 10993, and the company has conducted sterilization and shelf life validation in accordance with recognized industry standards.

Clinical testing included evaluation of 60 subjects treated with the Ascendx™ System and the Ascendx™ Cement. Outcomes evaluated included acute procedural success, pain, function, and adverse events including leakage and subsequent fractures. Follow-up was performed at discharge and 1, 3, 6, and 12 months post-treatment. Results were compared to an investigation using the same cement without the Ascendx™ in 113 subjects, as well as an investigation for 29 subjects undergoing treatment with the predicate device, and 31 subjects undergoing vertebroplasty. The results of this investigation demonstrated that the device could be used as intended to achieve pain and functional relief, and that the safety and effectiveness supported substantial equivalence to the predicate.

Substantial Equivalence

The Ascendx™ VCF Repair System is substantially equivalent to the predicate device. The Ascendx™ VCF Repair System has the same intended uses and indications as the predicate Kyphon Kyphx Inflatable Bone Tamp. Its technological characteristics and principles of operation are also similar to the predicate. The minor technological differences between the Ascendx™ VCF Repair System and its predicate device, e.g., with respect to dimensions, mechanism of cement delivery, etc., raise no new issues of safety or effectiveness, as confirmed by nonclinical and clinical testing.

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

AOI Medical, Incorporated
% Mr. Julian Mackenzie
President and CEO
7079 University Boulevard
Winter Park, Florida 32792

Letter dated: December 14, 2012

Re: K100404
Trade/Device Name: Ascendx™ VCF Repair System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN
Dated: October 9, 2012
Received: October 10, 2012

Dear Mr. Mackenzie:

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

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

Enclosure

Indications for Use Statement

510(k) Number (if known):_K100404__

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Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K100404