K093433

510(k) Summary of Safety and Effectiveness: Variax Elbow System Plate Line Extension

JAN 28 2010

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430
For Information contact:	Melissa A. Matarese, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5116 Fax: (201) 831-4116
Date Summary Prepared:	Nov 2, 2009

Device Identification

Proprietary Name:	Variax Elbow System Plate Line Extension
Common Name:	Bone plates and screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	HRS: Plate, Fixation, Bone

Description:

The subject VariAx Elbow System is comprised of plates and screws, manufactured from Titanium alloy and Commercially Pure Titanium. The subject system was determined substantially equivalent in K073527. This Special 510(k) submission is intended to address the shortening of the Distal Posterior Medial Humeral Plates, left and right. Two process changes, which have been documented internally and affect the entire Distal Posterior Medial humeral Plate family, are also discussed.

Intended Use:

The Variax Elbow System Plate Line Extension does not alter the intended use of the predicate systems as cleared in their respective premarket notifications. The indications for use for the subject plates are provided below.

Indications for Use:

The Variax Elbow System Plate Line Extension is intended for fracture fixation of long bones. Indications include distal humerus and proximal ulna.

Statement of Technological Comparison:

The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. Mechanical testing demonstrates substantial equivalence of the subject components to the predicate devise in regards to mechanical strength. In addition, the intended use, manufacturing methods, packaging, and sterilization of the predicate and subject components are identical.

The subject and predicate devices are made from Titanium alloy (Ti-6Al-4V) and Commercially Pure Titanium. Functional and mechanical testing demonstrates the comparable mechanical & functional properties of the subject Variax Elbow System Plate Line Extension to the predicate device VariAx Elbow System K073527.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Howmedica Osteonics Corp.
% Ms. Melissa A. Matarese
Regulatory Affairs Associate
325 Corporate Drive
Mahwah, New Jersey 07430

JAN 2 8 2010

Re: K093433
Trade/Device Name: VariAx Elbow System Plate Line Extension
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: January 14, 2010
Received: January 19, 2010

Dear Ms. Matarese:

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

Enclosure

Indications for Use

510(k) Number (if known): K093433

Device Name: VariAx Elbow System Plate Line Extension

Indications For Use:

The Variax Elbow System Plate Line Extension is intended for fracture fixation of long bones. Indications include distal humerus and proximal ulna.

Prescription Use ___X___ 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K093433

p. 1 of 1