K101056

510(k) Summary of Safety and Effectiveness

MAY 13 2010

Proprietary Name:	VariAx Elbow System
Common Name:	Bone plates and screws
Classification Name and Reference:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Regulatory Class:	Class II
Product Codes:	HRS: Plate, Fixation, Bone
For Information contact:	Melissa Matarese, Regulatory Affairs Associate Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5116 Fax: (201) 831-4116
Date Prepared:	April 13, 2010

Description:

Howmedica Osteonics is extending the indications for use of the VariAx Elbow System to improve clarity for the end user.

Intended Use:

The VariAx™ Elbow System is intended for fracture fixation of long bones. The indications for use provided below are have been modified compared to the predicate VariAx Elbow System's indications (K073527).

Indications:

Howmedica Osteonics is changing the indications for use of the VariAx Elbow System from "distal humerus and proximal ulna" to "Distal Humerus Plates are indicated for intra-articular or extra-articular fractures of the distal humerus, supracondylar fractures, osteotomies, and non-unions. Longer plates may be used for distal humerus fractures with diaphyseal extension.

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Olecranon Plates are indicated for intra-articular or extra-articular fractures of the proximal ulna, osteotomies, and nonunions. Longer plates may be used for proximal ulna fractures with diaphyseal extension."

Substantial Equivalence:

The features of the subject components are substantially equivalent to the predicate devices based on similarities in intended use and design. No mechanical tes ting was needed to demonstrate substantial equivalence of the subject components since no design changes were made to the system. In addition, the 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. The mechanical & functional properties of the subject VariAx Elbow System are identical 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 –WO66-G609
Silver Spring, MD 20993-0002

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

MAY 13 2010

Re: K101056
Trade/Device Name: VariAx Elbow Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: April 13, 2010
Received: April 15, 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): K101056

Device Name: VariAx Elbow System

Indications for Use:

Distal Humerus Plates are indicated for intra-articular or extra-articular fractures of the distal humerus, supracondylar fractures, osteotomies, and non-unions. Longer plates may be used for distal humerus fractures with diaphyseal extension. Olecranon Plates are indicated for intra-articular or extra-articular fractures of the proximal ulna, osteotomies, and nonunions. Longer plates may be used for proximal ulna fractures with diaphyseal extension.

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

for MXM

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

510(k) Number K101056

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