K112455 (1/2)

SEP 2 2 2011

510(k) Summary of Safety and Effectiveness:
VariAx® Distal Radius Locked Plating System Line Extension for Addition of Aiming Blocks

Sponsor: Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

Contact Person: Stephanie M. Fitts
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Mahwah, NJ 07430
Phone: (201) 831-5405

Date Prepared: August 16, 2011

Proprietary Name: VariAx® Distal Radius Locked Plating System Line Extension for addition of Aiming Blocks

Common Name: Bone plates and Screws

Classification Name: Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030

Device Product Code: 87 HRS: Plate, Fixation, Bone

Legally Marketed Device to Which Substantial Equivalence is Claimed: VariAx® Distal Radius Locked Plating System

Device Description:
This Special 510(k) submission is intended to add aiming blocks as an accessory to the VariAx® Distal Radius plate line which was cleared in K040022 and K100271. The aiming blocks are accessories used intra-operatively to guide the user in placement of the screws into the plate. There are 4 aiming blocks which correspond to the configurations of volar plates: Narrow Right, Narrow Left, Standard Right and Standard Left. The aiming blocks are used with a joystick tool which helps the user find the appropriate screw trajectory and is pinned in place once the desired alignment is obtained. Kirschner wires can also be used in conjunction with the aiming blocks to determine screw trajectory.

Intended Use:
The VariAx® Distal Radius Locked Plating System Line Extension addition of Aiming Blocks does not alter the intended use of the predicate system as cleared in K040022 and K100271. The indications for use for the subject plates are provided below.

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Indications for Use:
The VariAx® Distal Radius Plates are intended for use for internal fixation for fractures and reconstruction of the small bones, primarily including the distal radius. Examples of these internal fixations and reconstructions include compression fractures, intra-articular and extra-articular fractures, displaced fractures, osteotomies, non-unions and mal-unions. This system can be used for palmar, dorsal or orthogonal application.

Summary of Technologies:
The proposed device is substantially equivalent in intended use, materials and performance characteristics to the predicate device. Addition of the aiming block as an accessory to the bone plating system does not alter the technology.

Non-Clinical Testing:
Benchtop testing was conducted to demonstrate that the use of the aiming blocks as described in the operative technique could withstand clinically relevant loads. Torque to failure was performed using the joystick and the block assembled and failure loads were found to be acceptable. Lateral loads were also placed on the construct and the failure mode was disassembly without significant damage to the plate. Biocompatibility testing of the materials in the aiming block assembly (PEEK and stainless steel) was conducted as well as cleanability testing, sterility testing and corrosion resistance testing.

Clinical Testing:
Clinical testing was not required for this submission.

Conclusion:
The VariAx® Distal Radius Locked Plating System Line Extension addition of Aiming Blocks are substantially equivalent to the predicate devices identified in this premarket notification.

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 Corporation
% Dr. Stephanie Fitts
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325 Corporate Drive
Mahwah, New Jersey 07430

SEP 2 2 2011

Re: K112455
Trade/Device Name: VariAx® Distal Radius Locked Plating 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: August 16, 2011
Received: August 25, 2011

Dear Dr. Fitts:

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,

for 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): K112455

Device Name: VariAx® Distal Radius Locked Plating System

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Michael Owen for MXM

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

510(k) Number K112455