K100271 (1/2)

MAY 14 2010

510(k) Summary of Safety and Effectiveness

Proprietary Name:	VariAx Distal Radius Line Extension of XXL Plates
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:	October 20, 2009

Description:

Homedica Osteonics is extending the Variax Distal Radius Plates of the Variax Distal Radius Plating System to include XXL sized plates as well as to modify the indications for use for the XXL Volar Distal Radius Plates to include Osteotomies, non-unions and mal-unions.

Each plate will accept a locking screw, bone screws, locking pegs, and partially threaded screws. The XXL plates are precontoured performed for palmer, fixation. Screws are self-tapping and have either cross-pin or torx heads.

Plates are offerered in 5,8,11,and 15 hole options with a 2mm distal profile height and 3mm profile shaft height. All plates are straight and pre-contoured to fit the radial bow beyond the shaft. Gliding holes all for allignment of the plate and allow for additional bone reduction if required.

Intended Use:

The Stryker® XXL Volar Distal Radius Plates are intended for use for internal fixation for fractures and reconstruction of 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.

Indications:

The indications for use of The Stryker® XXL Volar Distal Plates Distal Radius Plates include:

The Stryker® XXL Volar 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.

Substantial Equivalence:

The VariAx Distal Radius Line Extension of XXL Plates is substantially equivalent to other commercially available plate systems in regard to intended use, design materials and operational principles. The following devices are examples of predicate systems: Stryker Leibinger Universal Distal Radius System (K040022) which is marketed under the name of VariAx Distal Radius System, Synthes Diaphyseal-Metaphyseal Volar Distal Radius Plate (K070946), and Zimmer Periarticular Locking Plate System (K040593). Based upon the mechanical testing, the VariAx Distal Radius Line Extension of XXL Plates is substantially equivalent for its intended use to other plating systems currently on the market. Also, the Distal Radius Torx Screws are compatible with this system (K080667).

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

MAY 14 2010

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

Re: K100271
Trade/Device Name: VariAX Distal Radius Line Extension of XXL Plates
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 29, 2010
Received: April 30, 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): K100271

Device Name: VariAx Distal Radius Line Extension of XXL Plates

Indications for Use:

The indications for use of the Distal Radius System:

The Stryker® XXL Volar 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.

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)

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

510(k) Number K100271