K060613

510(k) Summary of Safety and Effectiveness
VariAx™ Locking Plate System

APR 21 2006

Proprietary Name:	VariAx™ Locking Plate System
Common Name:	Bone plates and screws
Classification Name/Reference:	Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030
Device Product Code:	87 KTT
Proposed Regulatory Class:	Class II
For Information contact:	Vivian Kelly, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5581 Fax: (201) 831-6038
Date Summary Prepared:	March 6, 2006

Description

This submission is a line extension to the Numelock™ II System and the Stryker® Locked Plating System for various types of locking plates, locking screws and non-locking screws. Plates will be based on the design of the monoaxial plates in the Stryker® Locked Plating System and the polyaxial locking mechanism of the Numelock™ II plates. The subject plates have locking and non-locking holes and are used with the ∅4.0mm VariAx™ Universal Screws. There is a fully threaded, self-tapping screw and a partially threaded style of screw. All screws will be available sterile and non-sterile. The plates also have holes for standard Kirschner wires to enhance primary plate and fracture fixation or they can be used as suture anchors. Also, compression of the can be applied to the plate using the Universal Screw and act as a lag screw by pulling the bone toward the plate.

Indications:

The VariAx™ Locking Plate System is intended for use in the temporary stabilization of long bone fractures, including but not limited to:

- Proximal and distal fractures including joint fractures of the humerus, tibia and other long bones
- Metaphyseal, supracondylar, peri-articular, intra-articular, intra-articular condylar fractures
- Diaphyseal fractures
- Ankle fractures
- Simple, comminuted and depression fractures
- Non-unions and malunions
- Osteotomies and bone reconstruction
- Fractures in normal or osteoporotic bone

Substantial Equivalence:

The VariAx™ Locking Plate System is substantially equivalent to other plating systems in regards to intended use, design, materials, and operational principles as internal fixation components such as the Numelock™ II System, Stryker® Locked Plating System and the Stryker® Plating System. FEA and mechanical testing was conducted to compare the strength of the new plates and screws to other plates and screws on the market. The results demonstrate that the subject components are substantially equivalent in strength to the predicate components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2006

Howmedica Osteonics Corporation
c/o Ms. Vivian Kelly
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K060613
Trade/Device Name: VariAx™ Locking Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: March 6, 2006
Received: March 7, 2006

Dear Ms. Kelly:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060013

Device Name: VariAx™ Locking Plate System

Indications for Use:

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- Proximal and distal fractures including joint fractures of the humerus, tibia and other long bones
- Metaphyseal, supracondylar, peri-articular, intra-articular, intra-articular condylar fractures
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- Osteotomies and bone reconstruction
- Fractures in normal or osteoporotic bone

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) 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 General, Restorative, and Neurological Devices

510(k) Number K060013