K110176 #1/2



FEB 15 2011

## 510(k) Summary of Safety and Effectiveness:

## AxSOS® Locked Plating System Line Extension of 4mm Locking Inserts

**Sponsor**

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

**Contact Person**

Anthony Dennis
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**Date Prepared:** January 19, 2011

**Proprietary Name:** AxSOS® Locked Plating System Line Extension of 4mm Locking Inserts

**Common Name:** Bone plates and screws

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

21 CFR §888.3040
Smooth or Threaded metallic bone fixation fastener

**Legally Marketed Device to Which Substantial Equivalence is Claimed:**

Howmedica Osteonics Stryker Locked Plating System: K050512

**Device Description:** This Special 510(k) submission is intended to address modifications to the predicate Stryker Locking Inserts. The AxSOS® Locking Insert is being modified as part of a line extension of the AxSOS® Locked Plating System. The AxSOS® Locked Plating System contains 4mm Locking Inserts to which changes are being made to improve manufacturability. The locking inserts are made from stainless steel per ASTM F138 and ASTM F139. The AxSOS® Locked Plating 4.0mm Locking Inserts have similar or identical mechanical and material properties to the predicate 4.0mm Locking Inserts determined substantially equivalent via 510(k) K050512.

**Intended Use:** The AxSOS® Locked Plating System Line Extension of 4mm Locking Insert modifications do 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:**

The AxSOS Locked Plating System in the Stryker Locked Plating System is intended for use in long bone fracture fixation. The AxSOS Locked Plating System is indicated for fixation of long bone fractures including fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia, and the distal femur.

**Summary of Technologies:** The technological characteristics (material, design, sizes, and operational principles) of the AxSOS® Locked Plating 4.0mm Locking Inserts are similar or identical to the predicate device, K050512.

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The following mechanical/functional testing was performed: insertion force, screw insertion, push out, torsion, bending, and fatigue. The testing demonstrated that the AxSOS® Locked Plating 4.0mm Locking Inserts met performance requirements and are as safe and effective as their predicates.

**Clinical Testing:** None provided as a basis for substantial equivalence

**Conclusion:**
The AxSOS® Locked Plating 4.0mm Locking Inserts is substantially equivalent to the predicate devices identified in this pre-market 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 Corp.
% Mr. Anthony Dennis
325 Corporate Drive
Mahwah, New Jersey 07430

FEB 15 2011

Re: K110176
Trade/Device Name: AxSOS® Locked Plating System Line Extension of 4mm Locking Inserts
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 20, 2011
Received: January 21, 2011

Dear Mr. Dennis:

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): K 110176

Device Name: AxSOS® Locked Plating System Line Extension of 4mm Locking Inserts

Indications For Use:

The AxSOS Locked Plating System in the Stryker Locked Plating System are intended for use in long bone fracture fixation. The AxSOS Locked Plating System is indicated for fixation of long bone fractures including fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia, and the distal femur.

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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for M. Melkerson

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

510(k) Number K110176