

Summary of Safety and Effectiveness
Stryker Locked Plating System

Proprietary Name: Stryker Locked Plating System
Common Name: Bone Plate System
Classification Name and Reference: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR §888.3030
Proposed Regulatory Class: Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040 Class II
Device Product Code: 87 HRS: Plate, Fixation, Bone
87 HWC: Screw, Fixation, Bone
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: February 25, 2005

Description:

This Special 510(k) submission is intended to address modifications to the predicate Stryker Plating System.

Intended Use:

The subject and predicate devices are internal fixation plates, screws and accessories of the system. The Stryker Locked Plating System is intended for use in long bone fracture fixation. The new locking plates are indicated for fixation of long bone fractures including but not limited to fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia and the distal femur.

Substantial Equivalence:

The subject components share the same intended use, and basic design concepts as that of the currently available plates in the Stryker Plating System. Mechanical testing demonstrated comparable mechanical properties to the predicate components.



MAR 21 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Susan Krasny, Ph.D., RAC
Director of Clinical Research/Regulatory Affairs
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K050512

Trade/Device Name: Stryker Locked Plating System
Regulation Numbers: 21 CFR 888.3030, 21 CFR 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: HRS, HWC
Dated: March 26, 2005
Received: March 31, 2005

Dear Dr. Krasny:

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.

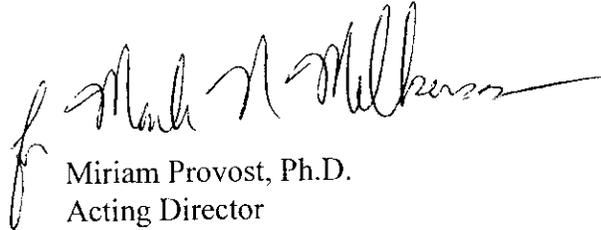
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", with a long horizontal flourish extending to the right.

Miriam Provost, Ph.D.
Acting 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):

Device Name: Stryker Locked Plating System

Indications for Use:

The SPS Monoaxial Locking Plates in the Stryker Locked Plating System are intended for use in long bone fracture fixation. The SPS Monoaxial Locking Plates are indicated for fixation of long bone fractures including but not limited to fractures of the distal radius, the proximal humerus, the distal tibia, proximal tibia and the distal femur.

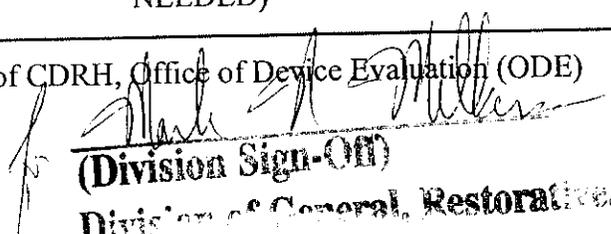
Prescription Use X
(Part 21 CFR 801 Subpart D)

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