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Summary of Safety and Effectiveness
Stryker® Plating System Line Extension

Proprietary Name:	Stryker® Plating System
Common Name:	Bone Plate System
Classification Name and Reference:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories, 21 CFR §888.3030 Smooth or Threaded Metallic Bone Fixation Fastener, 21 CFR §888.3040
Proposed Regulatory Class:	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:	March 23, 2006

Description:
This Special 510(k) submission is a line extension to address modifications to the Stryker® Plating System (SPS), which includes the SPS Small Fragment Set, the SPS Basic Fragment Set, the SPS Pelvic Set and the Stryker Locked Plating Set. This line extension is to add additional styles of plates based on the plates in the SPS Small Fragment Set and the SPS Basic Fragment Set.

Intended Use
The 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 indications for use for the predicate plates are provided below. The subject plates and subject accessories have the same indications as cleared their predicates.

SPS Small Fragment Set
The Stryker Plating System, Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

One third tubular plate: fibula, metatarsals, metacarpals
Fibular plate: fibula
Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
Oblique T-plate: distal radius
T-plate: distal radius, calcaneus, lateral clavicle

Cloverleaf plate: proximal humerus, distal tibia
Calcaneal plate: calcaneus
Reconstructive plate: humerus, pelvis

Screws are used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone.

SPS Basic Fragment Set
The Basic Fragment Set is intended for use in long bone fracture fixation.

Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited: to fractures of the femur, the tibia, the humerus and the pelvis.

T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

Substantial Equivalence:
These additional components are substantially equivalent to their predicate systems from the Stryker® Plating System in respect to design, intended use, performance and operational principle as internal fixation components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 12 2006

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

Re: K060798
Trade/Device Name: Stryker® 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, HWC
Dated: March 23, 2006
Received: March 24, 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.

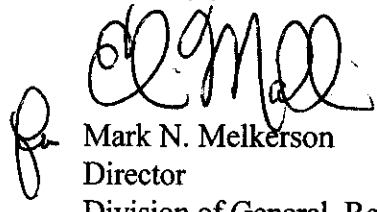
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Enclosure

K060798

Indications for Use

510(k) Number (if known):

Device Name: Stryker® Plating System

Indications for Use:

SPS Small Fragment Set

The Stryker® Plating System, Small Frag Set is indicated for fractures of the metaphysis and/or the diaphysis of the following:

One third tubular plate: fibula, metatarsals, metacarpals
Fibular plate: fibula
Compression plate: radius, ulna, distal tibia, fibula, distal humerus, clavicle
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SPS Basic Fragment Set

The Basic Fragment Set is intended for use in long bone fracture fixation. Reconstruction plates, wide and narrow straight and waisted compression plates are indicated for fixation of long bone fractures including but not limited: to fractures of the femur, the tibia, the humerus and the pelvis. T-plates, T-buttress plates and L-buttress plates are indicated for fractures at the proximal or distal end of long bones including but not limited to: fractures of the femoral condyles, the tibial plateau, the distal tibia and the proximal humerus.

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 K060798