K020772
page 1 of 1

510(k) Summary for the Omega® II System

Proprietary Name:	Omega® II System
Common Name:	Compression Hip Screw System
Classification Name and Reference	Single/multiple component metallic bone fixation appliances and accessories 21 CFR §888.3030
Regulatory Class:	Class II
Device Product Code:	87 KTT
For Information contact:	Karen Ariemma, Regulatory Affairs Specialist Howmedica Osteonics Corp. 59 Route 17 Allendale, NJ 07401-1677 Phone: (201) 760-8187 Fax: (201) 760-8435
Date Summary Prepared:	March 6, 2002

Description:
The Omega® II System is a compression hip screw system designed to treat various indications in the proximal femur. The Omega® II System consists of a range of Hip Plates, Lag Screws and a Compression Screw as well as the corresponding instruments. The Omega® II System is a modification to the existing Omega® + Plus System. The subject Omega® II Low Profile Hip Plate is shorter and has a thinner profile than the predicate Omega® + Plus Side Plate. The profile of the Omega® II Low Profile Hip Plate is similar to the design of the Synthes DHS Side Plate. The Omega® II Low Profile Hip Plates use the same Lag Screws as the predicate Omega® + Plus System.

Intended Use:
The Omega® II System is intended for use in the temporary stabilization of fractures of the proximal femur.

Substantial Equivalence:
The design and function of the Omega® II System is substantially equivalent to that of the predicate devices. Both the subject and predicate systems offer Hip Plates in varying lengths and angles, and offer a combination of Lag Screws, Compression Screws and Locking Screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 0 5 2002

Ms. Elizabeth Staub
Vice President, Quality Assurance/Regulatory Affairs/Clinical Research
Howmedica Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Re: K020772
Trade Name: Omega® II System
Regulatory Number: 21 CFR 888.3030
Regulatory Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: March 6, 2002
Received: March 8, 2002

Dear Ms. Staub:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 020772

Device Name: Omega® II System

Indications for Use

The Omega® II System is indicated for temporary stabilization of fractures of the proximal femur which may include the following:

- Intracapsular fractures of the femoral neck
- Intertrochanteric fractures

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020772