K034002
page 1 of 1

Special 510(k) Summary of Safety and Effectiveness:
Gamma3 Nail System Line Extension

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 325 Corporate Dr. Mahwah, NJ 07430
Contact Person:	Vivian Kelly Regulatory Affairs Specialist
Date of Summary Preparation:	December 23, 2003

Device Identification

Proprietary Name:	Gamma3 Nail System
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020

This Special 510(k) submission is a line extension intended to address modifications to the Gamma-Ti Nail System and the Gamma3 Nail System cleared in K013468 and K032244 respectively. The new components in the Gamma3 Nail System include additional sizes of Trochanteric Nails, Long Nails, shorter Lag Screws, additional Cap Screws and additional lengths of Locking Screws. The new components will be fabricated from the same material, titanium alloy, as the components in the predicate nail systems.

The Trochanteric Gamma3 Nails are intended for use in stabilizing various types of intertrochanteric fractures of the femur. The Long Length Gamma3 Nails are intended to be used in fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intracondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, mal-union, pathological fractures, and impending pathological fractures.

The material used to manufacture the line extension is identical to that of the predicate. Testing demonstrates the comparable mechanical properties of the subject Gamma3 Nail System to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 5 2004

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

Re: K034002
Trade/Device Name: Gamma3 Trochanteric Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: December 23, 2003
Received: December 24, 2003

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 (301) 594-4659. 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 Celia M. 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): K034002

Device Name: Gamma 3 Nail System

Indications For Use:

Gamma3 Trochanteric Nail

The intended use of the subject Trochanteric Gamma 3 Nail is identical to that of the predicate Trochanteric Gamma-Ti and Gamma® Nails. The product is intended for use in stabilizing various types of intertrochanteric fractures of the femur.

Long Length Gamma3 Nail

The product is intended to be used in fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intercondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, mal-union, pathological fractures, and impending pathological fractures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

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[illegible]ological [illegible]ces

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Prescription Use X OR Over-The-Counter Use ___

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