510(k) Summary of Safety and Effectiveness: Line Extension to the Gamma3® Nail System

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 325 Corporate Drive Mahwah, NJ 07430
Contact:	Jennifer Kosoy, Regulatory Affairs Specialist Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, NJ 07430 Phone: (201) 831-5601 Fax: (201) 831-6038 Email: jennifer.kosoy@stryker.com
Date Summary Prepared	December 9, 2004

Device Identification

Proprietary Name:	Gamma3® Nail System
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod and Accessories, 21 CFR §888.3020
Device Product Code:	87 HSB
Predicate Device:	Gamma3® Nail System, K034002 and K032244

Description

The Gamma3® Nail System is a family of intramedullary nails for basilar neck, intertrochanteric, subtrochanteric and femoral shaft fractures and consists of nails, lag screws, locking screws and set screws. The subject device is a line extension to the Gamma3® Nail System previously cleared in 510(k)s K034002 and K032244 to provide additional components and accessories to the system.

Intended Use

The intended use of the Gamma3® Nail System includes the following:

Trochanteric Gamma3® Nail

The Trochanteric Gamma3® Nail is intended for use in stabilizing various types of stable and unstable intertrochanteric fractures including peritrochanteric fractures.

Long Length Gamma3® Nail

The Long Length Gamma3® Nail is intended for fixation of stable and unstable femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intercondylar notch including fractures of the basilar neck, intertrochanteric fractures, peritrochanteric fractures, subtrochanteric fractures and femoral shaft fractures.

Indications for Use

The Trochanteric Gamma3® Nail is indicated for fixation of stable and unstable intertrochanteric fractures, including but not limited to nonunion, malunion and tumor resections, while the Long Length Gamma3® Nail indications may include fractures resulting from trauma, nonunion, malunion, pathological fractures, impending pathological fractures, tumor resections and revision procedures.

The Gamma3® U-Blade Lag Screw may be used with either the Gamma3® Trochanteric Nail or the Long Length Gamma3® Nail to treat patients with highly osteoporotic bone or metastatic disease in the femoral head, short femoral head/neck fragments, or unstable intertrochanteric fractures with missing medial-caudal bone support.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

Ms. Jennifer Kosoy
Regulatory Affairs Specialist
Howmedica Osteonics Corp
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K043431
Trade/Device Name: Line Extension to the Gamma® 3 Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Codes: HSB
Dated: December 10, 2004
Received: December 13, 2004

Dear Ms. Kosoy:

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.

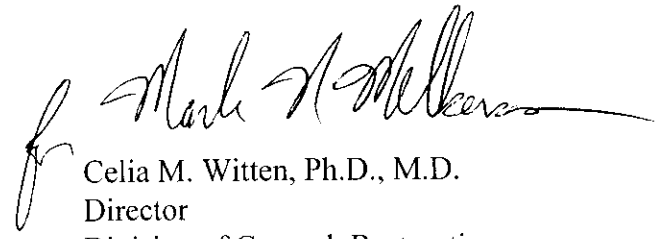
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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):

Device Name: Line Extension to the Gamma®3 Nail System

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Mark N Milliron

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

510(k) Number K043431