



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 28 2005

Ms. Vivian Kelly
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Re: K032244

Trade/Device Name: Gamma 3 Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: July 16, 2003
Received: July 22, 2003

Dear Ms. Kelly:

This letter corrects our substantially equivalent letter of August 8, 2003 regarding the Regulation Number, Regulation Name and Product Code of the above device. The correct information is listed above.

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 (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 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.

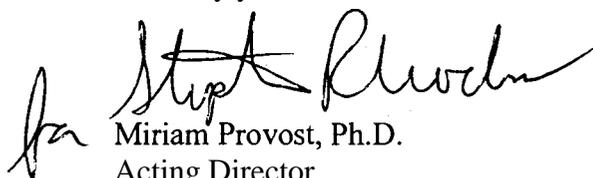
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 continue 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,

A handwritten signature in black ink, appearing to read "Miriam Provost". The signature is written in a cursive style with a large initial "M".

Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032244

Device Name: Gamma 3 Nail System

Indications For Use:

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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number — K032244 —

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use —

OR

Over-The-Counter Use —

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

AUG - 8 2003
Summary of Safety and Effectiveness

K032044
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Line Extension to the Trochanteric Dyax® & Gamma® Nail Systems

Submission Information

Name and Address of the Sponsor of the 510(k) Submission: Howmedica Osteonics Corp
59 Route 17
Allendale, NJ 07401-1677

Contact Person: Vivian Kelly
Regulatory Affairs Consultant
Phone: 201-831-5581
Fax: 201-831-6038

Date of Summary Preparation: July 16, 2003

Device Identification

Proprietary Name: Gamma 3 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 to the Trochanteric Dyax® and Gamma® Nail Systems. This line extension is intended to address a material modification and design modifications to the predicate Trochanteric Dyax® and Gamma® Nail Systems. Both the subject and predicate systems offer trochanteric nails, and offer various accessories such as lag screws, locking screws, set screws, and end caps.

The intended use of the subject device is identical to that of the predicate Trochanteric Dyax® Nails. The device is intended for use in stabilizing various types of intertrochanteric fractures of the femur. The Trochanteric Gamma 3 Nail in the Gamma 3 Nail System also has the same basic design concepts as the currently available Trochanteric Dyax® and Gamma® Nail Systems. Mechanical testing demonstrated comparable mechanical properties to the predicate components.