K013524

Special 510(k) Summary of Safety and Effectiveness:

NOV 1 4 2001

Line Extension to the Trochanteric Gamma® Nail System

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:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	October 22, 2001

Device Identification

Proprietary Name:	Trochanteric Dyax Nail System (formerly the Trochanteric Gamma® Nail System)
Common Name:	Intramedullary Nail
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020

This Special 510(k) submission is intended to address a material modification and design modifications to the predicate Trochanteric Gamma® Nail System. The subject device, named the Trochanteric Dyax Nail System, is a line extension of the Trochanteric Gamma® Nail System. The predicate Trochanteric Gamma® Nail System is fabricated from stainless steel. The subject Trochanteric Dyax Nail System is fabricated from titanium alloy. The design change for the nail involves changing the proximal diameter and changing the distal screw hole diameter and configuration. The 5 mm diameter fully threaded locking screws from the T2 Nail System will be compatible with the Trochanteric Dyax Nail.

The predicate Trochanteric Gamma® Nails an intramedullary rod intended to be used for stabilizing various types of intertrochanteric fractures of the proximal femur. There is no change in intended use for the modified device when compared to the previously cleared product. The subject Trochanteric Dyax Nails are substantially equivalent to the existing design of Trochanteric Gamma® Nails which were determined substantially equivalent via the 510(k) process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2001

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K013524
Trade/Device Name: Trochanteric Dyax Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 22, 2001
Received: October 23, 2001

Dear Ms. Ariemma:

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 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

K013524

NOV 1 4 2001

510(k) Number (if known): K013524

Device Name: Trochanteric Dyax Nails (line extension to the Trochanteric Gamma® Nail)

Indications For Use:

The device is intended for use in stabilizing various types of intertrochanteric fractures of the proximal femur.

(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 K013524