

NOV 18 1998

K983358

510(k) Summary

Proprietary Name: G/K Locking Nail System  
Common Name: IM Rod  
Classification Name & Reference: Intramedullary Fixation Rod  
21 CFR 888.3020  
Proposed Regulatory Class: II  
Device Product Code: 87HSB

For information contact: Vivian Kelly  
Manager, Regulatory Affairs  
Howmedica Inc.  
359 Veterans Boulevard  
Rutherford, NJ 07070  
Telephone: (201) 507-7830  
Fax: (201) 507-6870

Date prepared: September 23, 1998

The G/K Locking Nail System is a family of intramedullary rods intended to provide temporary stabilization of various types of fractures, osteotomies, malunions and nonunions of the femur and tibia. Other types of procedures include reconstruction, bone lengthening/shortening, prophylactic nailing of impending fractures and fusions.

This G/K line extension includes solid femoral nails (SFN) and solid tibial nails (STN) which may be used with cross-locking screws for intramedullary nailing of femoral and tibial fractures, respectively. The nails can be inserted with or without reaming using an opened or closed technique. They can be locked statically or dynamically. Also, there is an optional nail plug available to prevent tissue infiltration. All of the components are fabricated from medical grade stainless steel.

The substantial equivalence of this device is based on an equivalence in intended use, materials, designs and operational principles to Synthes' Universal Femoral Nail and Unreamed Tibial Nail and Orthofix's Tibial Nailing and Femoral Nailing Systems.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Ms. Vivian Kelly  
Manager, Regulatory Affairs  
Howmedica Inc.  
Pfizer Medical Technology Group  
359 Veterans Boulevard  
Rutherford, New Jersey 07070-2584

Re: K983358  
Trade Name: G/K Locking Nail Line Extension  
Regulatory Class: II  
Product Code: HSB  
Dated: September 23, 1998  
Received: September 24, 1998

Dear Ms. Kelly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

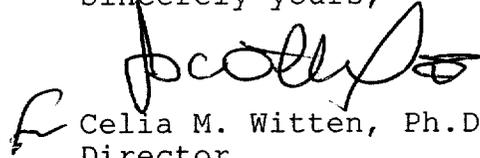
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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

Enclosure

## Indications for Use

510(k) Number (if known):

Device Name: G/K Locking Nail System

Indications for Use:

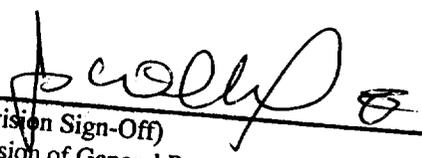
The G/K Locking Nail System is a family of intramedullary rods intended to provide temporary stabilization of various types of fractures, osteotomies, malunions and nonunions of the femur and tibia. Other types of procedures include reconstruction, bone lengthening/shortening, prophylactic nailing of impending fractures and fusions.

(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)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K983358