



WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

K971135

JUN - 5 1997

Contact Person: Cristie Manuel
Date: March 26, 1997

510(k) Summary

Trade/Proprietary Name: MAGELLAN™ Intramedullary Nail System
Common Name: Intramedullary Fixation Rod and Accessories
Classification: Class II
Predicate Device: MAGELLAN™ Femoral Nail manufactured by Wright Medical Technology, Inc. and the Russell-Taylor Femoral Nail System manufactured by Smith and Nephew

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Indicated Use

The MAGELLAN™ Intramedullary Femoral Nail System is a modular system consisting of femoral nails, femoral rod inserts, nail caps, locking screws, and instrumentation for fixation. The system is made of 316 LVM stainless steel conforming to ASTM F 138. The nail is available in six outer diameters and eight lengths. The nail may be cross-locked dynamically or statically, locked antegrade, and also has reconstruction capabilities.

This MAGELLAN™ Magnetic distal targeting instrumentation system is designed to locate and lock in place the distal screw holes of the Magellan Intramedullary Femoral Nail without the use of radiographic equipment. The system includes reamers for preparing the intramedullary canal for nail placement; a targeting compass and magnetic target insert that locate the distal screw holes, and targeting Steinmann pins and drill bits (two sizes) that create the proximal and distal screw holes. This instrument system is used with power equipment available from other manufacturers, and is certified by the supplier to work with the power source.

The MAGELLAN™ Intramedullary Femoral Nail System is indicated for use in long bone shaft fractures of the femur which require stabilization of the axis of the bone, including subtrochanteric fractures, intertrochanteric fractures, femoral neck fractures, comminuted fractures, segmental fractures, fractures with bone loss, proximal and distal fractures, nonunions and malunions, and bone lengthening.

Testing

Testing and theoretical data show that the MAGELLAN™ nail device has appropriate strength for clinical usage, and will perform similarly to the Russell-Taylor System.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 1997

Ms. Cristie Manuel
Regulatory Affairs Associate
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K971135
MAGELLAN™ Intramedullary Femoral Nail System
Regulatory Class: II
Product Code: HSB
Dated: March 26, 1997
Received: March 27, 1997

Dear Ms. Manuel:

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.

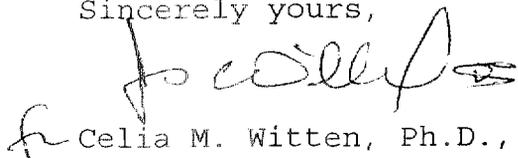
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 pre-market 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.

Page 2 - Ms. Cristie Manuel

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

C. Indications for use of the Device

Page 1 of 1

510(k) Number (if known): _____

Device Name: **MAGELLAN™ Intramedullary Femoral Nail System**

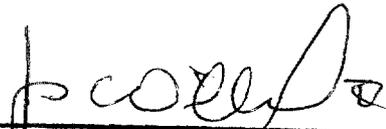
Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K9 71135

Prescription Use X
(Per 21 CFR 801.109)

Or

Over-the-Counter Use _____
(Optional Format 1-2-96)

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