

OCT - 3 1997



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

K971056

Contact Person: Cristie Manuel
Date: March 21, 1997

510(k) Summary

Trade/Proprietary Name: MAGELLAN™ Magnetic Distal Targeting System
(proposed name), Product Line Extension
Common Name: Surgical instrument motors and accessories/attachments
Classification: Class I
Predicate Device: Preamendments Intramedullary Nail Instrumentation
(Wright Medical Technology, Inc.) Russell-Taylor
Intramedullary Nail System Instrumentation (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™ Magnetic Distal Targeting 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; drill bits to drill screw holes proximally, a targeting compass and magnetic target insert to locate the distal screw holes, and targeting Steinmann pins and drill bits (two sizes) to create the 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™ Magnetic Distal Targeting 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

Because the MAGELLAN™ Magnetic Distal Targeting System is substantially equivalent to the predicate device in design, material, and intended use, testing was not performed.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

Ms. Kim Tompkins
Director
Clinical and Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, Tennessee 38002

Re: K971056
Trade Name: MAGELLAN Magnetic Distal
Targeting System
Regulatory Class: II
Product Code: HSB
Dated: July 3, 1997
Received: July 7, 1997

Dear Ms. Tompkins:

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.

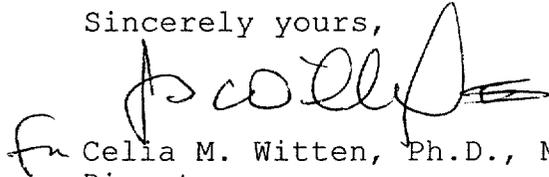
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Kim Tompkins

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,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

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™ Magnetic Distal Targeting System**

Indications for Use:

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.

(Please do not write below this line—continue on another page if needed)

* * * * *

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971056

Prescription Use
(Per 21 CFR 801.109)

Or

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

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