K024336

MAR 0 4 2003

WRIGHT MEDICAL TECHNOLOGY

A Wright Medical Group Company

510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the MIIG™ II.

Submitted By:	Wright Medical Technology, Inc.
Date:	February 22, 2001
Contact Person:	Ehab M. Esmail Manager, Regulatory Affairs **Phone:** 901-867-4732 **Fax:** 901-867 4630
Proprietary Name:	MIIG™ II
Common Name:	Bone Void Filler
Classification Name and Reference:	Unclassified
Device Product Code and Panel Code:	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The MIIG™ paste is intended to be injected into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis) and to cure *in-situ*. These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The MIIG™ paste provides a bone void filler that resorbs and is replaced with bone during the healing process.

The MIIG™ paste cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g., K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

The MIIG™ II is provided sterile for single use only.

B. DEVICE DESCRIPTION

The MIIG™ II paste consists of pre-measured surgical grade calcium sulfate, pre-measured mixing solution, and the tools necessary to the components into a paste and inject the material into the defect site. These products are provided sterile for single patient use. When mixed and injected according to directions, MIIG™ II paste will harden *in situ* and provide temporary intra-operative support to a site prior to the fixation of final hardware. The MIIG™ II product has been developed to address the identical indications as the MIIG™ product.

C. MATERIALS

The materials used for the MIIG™ II are substantially equivalent to the previously submitted and cleared MIIG™.

	MIIG™	MIIG™ II
POWDER	MIIG™ Powder	MIIG™ II Powder
	• Surgical Grade Calcium Sulfate Hemihydrate • Accelerator • Setting Additive	• Surgical Grade Calcium Sulfate Hemihydrate • Accelerator
LIQUID	Diluent	Diluent
	• Saline Irrigation	• Sterile Water for Irrigation

D. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material composition, and design features of the MIIG™ II are substantially equivalent to the intended use, material composition, and design features of the previously submitted and cleared MIIG.

The safety and effectiveness of the MIIG™ II is adequately supported by the substantial equivalence information, materials data, and testing results provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 4 2003

Mr. Ehab M. Esmail
Manager, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Re: K024336
Trade/Device Name: MIIG™ II
Regulatory Class: Unclassified
Product Code: MQV
Dated: February 11, 2003
Received: February 12, 2003

Dear Mr. Esmail:

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), please contact the Office of Compliance at (301) 594-4659. 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,

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

WRIGHT MEDICAL TECHNOLOGY

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MIIG™ II

INDICATIONS STATEMENT

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The MIIG™ paste cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g., K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

The MIIG™ is provided sterile for single use only.

for Mark N Milligan

(Division Sign-Off)
Division of Gene l, Restorative
and Neurological Devices

510(k) Number K024336

(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 _____

Prescription Use ✓
(Per21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)