K024180

510 (k) SUMMARY

MAR 1 4 2003

I. ADMINISTRATIVE

Submitter: MPM Medical, Inc.
2301 Crown Court
Irving, Texas 75038
(982) 893-4060

Contact Person: Paul R. Miller

Date of Preparation: February 25, 2003

II. DEVICE NAME

Proprietary Name: OraMagicRx™ Oral Wound Rinse
Common Name: Mucositis/Stomatitis Oral Rinse
Classification Name: Dressing, Wound and Burn, Hydrogel w/ Drug and/or Biologic

III. PREDICATE DEVICE

Radiacare™ Oral Wound Rinse (K964852 Carrington Laboratories, Inc.)

IV. DEVICE DESCRIPTION

OraMagicRx™ Oral Wound Rinse is a wound dressing designed for the management of oral mucositis/stomatitis. The device is supplied in plastic bottles containing 7.1 g, 25 g or 37.5 g of dry powder for reconstitution with water prior to use.

V. INTENDED USE

For the management of mucositis/stomatitis, all types of oral wounds (mouth sores and injuries), aphthous ulcers/canker sores, and traumatic ulcers caused by ill-fitting dentures or braces.

The biocompatibility of this device has been established by a primary dermal irritation test in rabbits, a sensitization test in guinea pigs, and an *in vitro* cytotoxicity test.

VI. COMPARISON TO PREDICATE DEVICE

OraMagicRx™ Oral Wound Rinse is similar in composition, and identical in function and intended use, to Radiacare™ Oral Wound Rinse (Carrington Laboratories, Inc.) and other legally marketed hydrogel wound dressing products.

Accordingly, MPM Medical concluded that OraMagicRx™ Oral Wound Rinse is safe and effective for its intended use, and performs at least as well as legally marketed predicate devices, such as Carrington's Radiacare™ Oral Wound Rinse

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2003

MPM Medical, Incorporated
C/O Mr. Richard Hamer
Consultant
Richard Hamer Associates, Incorporated
48910 Denton Road, # 38
Belleville, Michigan 48111

Re: K024180
Trade/Device Name: OraMagicRx™ Oral Wound Rinse
Regulation Number: None
Regulation Name: Mucositis/Stomatitis Oral Rinse
Regulatory Class: Unclassified
Product Code: MGQ
Dated: December 17, 2002
Received: December 18, 2002

Dear Mr. Hamer:

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) 594-4613. 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K024180

Device Name: OraMagicRx™ Oral Wound Rinse

Indications for Use:

For the management of oral mucositis/stomatitis, all types of oral wounds (mouth sores and injuries), aphthous ulcers/canker sores, and traumatic ulcers such as those caused by ill-fitting braces or dentures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MSK

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K024180

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____

(Optional Format 1-2-96)