K971622

MPL Technologies
A SoloPak® Company

JUN 20 1997

510(k) SUMMARY

June 13, 1997

To Whom it may concern:

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and CFR 807.92:

Trade Name - Max-i-Probe Endodontic Sealer Delivery System
Common Name - Endodontic Sealing Cement
Classification Name - Root Canal Filling resin (21CFR § 872.3820)

The MPL Technologies Inc. Max-i-Probe Endodontic Sealer Delivery System is intended to be used in endodontic therapy by dental care professional in a clinical setting to apply Zinc Oxide-Eugenol sealing cement to the inside surface of a prepared root canal prior to the introduction of gutta percha (or other restorative and filling materials).

The Max-i-Probe Endodontic Sealer Delivery System consists of Zinc Oxide/Eugenol dental cement packaged in a delivery cartridge consisting of a type 304 stainless steel tube insert molded into a nylon cartridge. A sealer cartridge is loaded into a cartridge-type syringe. The tube is inserted into the prepared canal. The cement is expressed directly into the canal by squeezing the pressure activation handle while slowly withdrawing the probe from the canal. The cement is allowed to set. The empty cartridge is removed and discarded.

The manufacturing materials and processes, and functionality of the Max-i-Probe Endodontic Sealer Delivery System are the same or equivalent as the predicate device/devices named in the submission: Roth International Ltd. Root Canal Cement, Type 801 Elite Grade/Eugenol USP.

Each Max-i-Probe Endodontic Sealer Delivery System cartridge is packaged in a sealed polypropylene cartridge pak and radiation sterilized to AMI guidelines. The sterility assurance level is at least 10^{-6}. Each lot is dosimetrically released.

Based on the fact that the Max-i-Probe Endodontic Sealer Delivery System utilizes similar and equivalent designs, components, manufacturing processes as currently legally marketed products, this product is safe and effective when used as intended.

Sincerely,

Daniel J. Østerby
Quality Assurance Director
MPL Technologies, Inc.

MPL Technologies Inc. 9400 King Street Franklin Park, Illinois 60131-2116 Telephone: 847-678-7555 Telefax: 847-678-7585

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Mr. Daniel J. Osterby
Quality Assurance Director
MPL Technologies, Incorporated
9400 King Street
Franklin Park, Illinois 60131

Re: K971622
Trade Name: Max-I-Probe Endodontic Sealer Delivery System
Regulatory Class: II
Product Code: KIF
Dated: April 10, 1997
Received: May 2, 1997

Dear Mr. Osterby:

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 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 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.

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) 594-4618. 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 at (301) 443-6597.

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971622

Device Name: Max-i-Probe Endodontic Sealer Delivery System

Indications For Use:

This device is intended to be used in endodontic therapy as an improved method for applying Zinc Oxide-Eugenol sealing cement directly to the inside surface of a prepared root canal to coat and seal the canal walls prior to the introduction of gutta percha (or other restorative and filling materials).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971622

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)