510(k) SUMMARY

DENTSPLY

MAY - 2 2001

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
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P. J. Lehn Telefax (717) 849-4343

K011009

CONTACT: P. Jeffery Lehn

DATE PREPARED: April 3, 2001

TRADE OR PROPRIETARY NAME: WHITE MTA MATERIAL

CLASSIFICATION NAME: Root canal filling resin 872.3820

PREDICATE DEVICES:

MTA Material II	K981620
MTA Material	K980332
Mineral Trioxide Aggregate	K964174

DEVICE DESCRIPTION: WHITE MTA MATERIAL is a tooth-colored powder consisting of fine hydrophilic particles. Hydration of the powder results in a colloidal gel, which solidifies to form a strong impermeable barrier. It seals off all pathways of communication between the root canal system and the external surface of the tooth.

INTENDED USES FOR WHITE MTA MATERIAL:

- Repair of root perforations during root canal therapy (endodontic therapy), or as a consequence of internal resorption
- Repair of root canals as an apical plug during apexification
- Root end filling
- Pulp capping

TECHNOLOGICAL CHARACTERISTICS: All of the components found in WHITE MTA MATERIAL have been used in the legally marketed predicate device.

The material was evaluated and found to be non-mutagenic and non-cytotoxic.

Therefore, we believe that the prior use of the components of WHITE MTA MATERIAL in the legally marketed predicate device, the performance data, and the results of biocompatibility testing support the safety and effectiveness of WHITE MTA MATERIAL for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2001

P. Jeffery Lehn
Director of Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
York, Pennsylvania 17404

Re: K011009
Trade/Device Name: White MTA Material
Regulation Number: 872.3820
Regulatory Class: II
Product Code: KIF
Dated: April 3, 2001
Received: April 4, 2001

Dear Mr. Lehn:

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 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). 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 requirements, 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.

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) 594-4692. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

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

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K011009

Device Name: WHITE MTA MATERIAL

Indications for Use:

- Repair of root perforations during root canal therapy (endodontic therapy), or as a consequence of internal resorption;
- Repair of root canals as an apical plug during apexification;
- Root end filling material; and
- Pulp capping material

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011009

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)