K080203

510(k) SUMMARY

MAR 26 2008

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT:	Helen Lewis
DATE PREPARED:	January 23, 2008
TRADE OR PROPRIETARY NAME:	MTA ROOT CANAL SEALER
CLASSIFICATION NAME:	Root canal filling resin (872.3820, KIF)
PREDICATE DEVICES:	MTA Advanced Material K073218

DEVICE DESCRIPTION: The MTA ROOT CANAL SEALER is a powder and liquid root canal sealer system. The combination of the powder and liquid creates a colloidal gel that solidifies to form a strong impermeable barrier to seal off pathways of communication between the root canal system and external surfaces of the tooth.

INTENDED USES: MTA ROOT CANAL SEALER is for the permanent sealing of root canals of teeth and may be used in combination with root canal obturation materials.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in MTA ROOT CANAL SEALER have been used in legally marketed devices and/or were found safe for dental use. MTA ROOT CANAL SEALER has been evaluated and passed biocompatibility testing for cytotoxicity, mutagenicity, sensitization and endodontic usage.

SUPPORT OF SUBSTANTIAL EQUIVALENCE: DENTSPLY considers the proposed MTA Root Canal Sealer to be substantially equivalent to the legally marketed MTA Advanced Material (K073218, cleared January 7, 2008). The results of biocompatibility testing have shown that MTA ROOT CANAL SEALER does not raise any new safety/biocompatibility concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Helen Lewis
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International, Incorporated
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

Re: K080203
Trade/Device Name: MTA ROOT CANAL SEALER
Regulation Number: 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: January 23, 2008
Received: January 28, 2008

Dear Ms. Lewis:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K080203

Device Name: MTA ROOT CANAL SEALER

Indications for Use:

MTA ROOT CANAL SEALER is indicated for use for the permanent sealing of root canals of teeth and may be used in combination with root canal obturation materials.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

RBBeth DDS for Dr. S. Runner

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

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