510(k) SUMMARY

JAN - 7 2008

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

CONTACT: Helen Lewis

DATE PREPARED: NOV 08 2007

TRADE OR PROPRIETARY NAME: MTA ADVANCED MATERIAL

CLASSIFICATION NAME: Root canal filling resin 872.3820

PREDICATE DEVICES: White MTA Material K011009

DEVICE DESCRIPTION: MTA ADVANCED MATERIAL is a powder and liquid root canal treatment 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 USE: MTA ADVANCED MATERIAL is indicated for use in dental procedures that contact the pulp, dentin, or periradicular tissues:
- Repairing the periradicular tissues in procedures such as root-end filling, repair of internal or external root resorption, iatrogenic perforation repair, apexification, pulpectomy, or
- For protecting injured pulps, pulp-capping, pulpotomies, or cavity liner

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

We believe that the prior use of the components of MTA ADVANCED MATERIAL in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of MTA ADVANCED MATERIAL for the indicated uses.
Ms. Helen Lewis  
Director of Corporate Compliance and Regulatory Affairs  
DENTSPLY International  
Susquehanna Commerce Center  
221 West Philadelphia Street, Suite 60  
York, Pennsylvania 17405-0872

Re: K073218
  Trade/Device Name: MTA Advanced Material  
  Regulation Number: 21 CFR 872.3820  
  Regulation Name: Root Canal Filling Resin  
  Regulatory Class: II  
  Product Code: KIF  
  Dated: November 8, 2007  
  Received: November 20, 2007

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" (21 CFR 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): 120473218

Device Name: MTA ADVANCED MATERIAL

Indications for Use:
MTA ADVANCED MATERIAL is indicated for use in dental procedures that contact the pulp, dentin, or periradicular tissues:
- Repairing the periradicular tissues in procedures such as root-end filling, repair of internal or external root resorption, iatrogenic perforation repair, apexification, pulpectomy, or
- For protecting injured pulps, pulp-capping, pulpotomies, or cavity liner

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

Sue K. Reeder

Premarket Notification  MTA ADVANCED MATERIAL  DENTSPLY International