

510(k) SUMMARY

DENTSPLY

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NAME & ADDRESS:

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: MAY 8, 1998

TRADE OR PROPRIETARY NAME: MTA MATERIAL

COMMON OR USUAL NAME: Root Filling Material

CLASSIFICATION NAME: Root canal filling resin material 872.3820

PREDICATE DEVICE: Mineral Trioxide Aggregate K964174
MTA Material K980332

DEVICE DESCRIPTION: MTA MATERIAL is identical to K964174 and K980332. This submission is for a new intended use.

MTA MATERIAL is a powder consisting of fine hydrophilic particles. Hydration of the powder results in a colloidal gel, which solidifies to a hard structure.

INTENDED USE: MTA MATERIAL is indicated for use as a root end filling material.

TECHNOLOGICAL CHARACTERISTICS: MTA MATERIAL is identical to DENTSPLY'S K964174 and K980332. This submission is for an additional intended use.

The fact that the formula is identical to K964174 and K980332 leads to the conclusion that biocompatibility studies with the formulation are not necessary

Therefore, we believe that the prior use of the formula in K964174 and K980332, the in-vitro and animal study performance data provided, and the results of previous testing in K964174 support the safety and effectiveness of MTA MATERIAL for the new intended use.

Substantial Equivalence Comparison:

ID of Predicate Device:

K964174 and K980332 are the predicate devices for this submission. MTA MATERIAL is identical to the predicates. This submission is for a new intended use only.

Statement of Similarities and/or Differences:

MTA MATERIAL is identical to K964174 and K980332. This submission is for a new intended use only.

- This submission addresses the new intended use: *Root end filling material.*
- K980332 addresses the uses: *Repair of root canals as an apical plug during Apexification, and repair of Root Perforations during root canal therapy (endodontic therapy) or as a consequence of internal resorption.*
- K964174 addresses the use: *Intended to be applied to a tooth to protect the pulp.*



JUL 3 | 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. P. Jeffrey Lehn
Director, Corporate Compliance
and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K981620
Trade Name: MTA Material II
Regulatory Class: II
Product Code: KIF
Dated: May 5, 1998
Received: May 6, 1998

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 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.

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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" (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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

T. A. Ulatowski for

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

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(K) Number: _____

Device Name: MTA MATERIAL II

MTA MATERIAL II is indicated for use as a root end filling material.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Skinner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K98162C

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