

K980332

**510(k) SUMMARY** FEB 24 1998



**NAME & ADDRESS:**

**DENTSPLY International**  
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**CONTACT:** P. Jeffery Lehn

**DATE PREPARED:** January 23, 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

**DEVICE DESCRIPTION:** MTA MATERIAL is identical to K964174, Mineral Trioxide Aggregate (found substantially equivalent February 10, 1997). 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 the 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.

**TECHNOLOGICAL CHARACTERISTICS:** MTA MATERIAL is identical to DENTSPLY'S K964174, Mineral Trioxide Aggregate. This submission is for an additional intended use.

The fact that the formula is identical to K964174 (found substantially equivalent February 10, 1997) 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, the 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.

**000012**

## **Substantial Equivalence Comparison:**

### **ID of Predicate Device:**

**K964174, Mineral Trioxide Aggregate, is the predicate device for this submission. MTA MATERIAL is identical to the predicate. This submission is for a new intended use only.**

### **Statement of Similarities and/or Differences:**

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

- **This submission addresses the new intended use: *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.***

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## **Performance Data:**

The use of MTA MATERIAL to repair root canals as an apical plug during Apexification, and to repair Root Perforations during root canal therapy (endodontic therapy) or as a consequence of internal resorption is addressed in Exhibits 1 through 4.

### **Non-Apical Root Perforation Repair (Exhibit 1)**

The ability of MTA MATERIAL to seal non-apical (lateral) root perforations was investigated in an in-vitro extracted tooth model, which compared its performance to IRM® filling material and amalgam. In this dye penetration study, the MTA MATERIAL showed the least degree of dye leakage. There was no significant statistical difference between the IRM and amalgam groups, while MTA leaked significantly less than the other two materials ( $p < 0.05$ ). Even when perforations were overfilled or underfilled, MTA MATERIAL still had the least dye penetration associated with it when compared to IRM and amalgam ( $p < 0.05$ ).

### **Furcal Perforations (Exhibit 2)**

The suitability of MTA MATERIAL for the repair of furcal perforations was investigated in a study with seven dogs, which compared its performance to that of amalgam. In half of the teeth, the perforation was filled immediately with either amalgam or MTA MATERIAL. In the other half the perforations were left open to salivary contamination for six weeks to allow for bacterial contamination and the formation of inflammatory lesions in the furcation, after which time the perforations were cleaned and filled with either amalgam or MTA MATERIAL. Histological examination after four months showed only one of six teeth repaired immediately with MTA MATERIAL exhibited inflammation, while all perforations filled with amalgam had inflammation associated with them, that was often moderate to severe. In addition five of the six teeth filled with MTA MATERIAL had some cemental repair over the material. Those perforations that were allowed to remain open and then repaired, exhibited inflammation in four of seven teeth filled with MTA MATERIAL. Those filled with amalgam were all associated with inflammation that was frequently severe and more extensive.

### **Apical Plug During Apexification (Exhibit 3)**

The ability of MTA MATERIAL to serve as an apical barrier was evaluated in a study with seven dogs. Following preparation of the root canals, periapical lesions were induced by allowing the canals to remain open for 14 days and then sealing them with zinc oxide-eugenol cement for 14 days. All infected canals were then cleaned, shaped and irrigated with sodium hypochlorite. Calcium hydroxide was placed in the canals as a disinfectant for one week and then removed. MTA was placed in the canals and condensed. Evaluations were made after nine weeks. The MTA MATERIAL had the smallest lesions histologically and radiographically of all of the experimental materials investigated, and functioned well as a one-step apical plug material in an open apex.

### **Apical Plug During Apexification (Exhibit 4)**

The comparative efficacy of osteogenic protein-1 (OP-1), calcium hydroxide, and MTA MATERIAL to form a hard tissue barrier in immature roots was evaluated in dogs. The amount of hard tissue formation and the degree of inflammation were evaluated histomorphometrically. MTA MATERIAL induced apical hard tissue formation more often than the other test materials ( $p = 0.004$ ). The degree of inflammation, in ascending order, was MTA MATERIAL, calcium hydroxide, OP-1, and collagen carrier alone. No significant statistical differences in the degree of inflammation were found. Based on the results, MTA MATERIAL can be used as an apical barrier for apexification in immature roots.

**000014**

## **Safety Data:**

**MTA MATERIAL is identical to DENTSPLY'S K964174, Mineral Trioxide Aggregate. This submission is for an additional intended use.**

**The fact that the formula is identical to K964174 (found substantially equivalent February 10, 1997) results in the decision that biocompatibility studies with the final formulation are not necessary.**

**Therefore, we believe that the prior use of the formula in K964174, the 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.**

**000015**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 24 1998

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: K980332  
Trade Name: MTA Material  
Regulatory Class: II  
Product Code: KIF  
Dated: January 23, 1998  
Received: January 28, 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 current Good Manufacturing Practice requirement, 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

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

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

**PREMARKET NOTIFICATION**  
**INDICATIONS FOR USE STATEMENT**

510(K) Number: K980332

Device Name: MTA MATERIAL

MTA MATERIAL is indicated for the 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.

Susan Rumba  
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(Division Sign-Off)  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K980332  
Prescription Use  OR Over-The-Counter Use

(Per 21 CFR 801.109)