

JAN 1 8 2000

K 992727

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

MDS
119 West 57th Street Suite 700
New York, NY 10019

Date Summary Prepared: August 4, 1999

Contact: Dr. Barry Lee Musikant

2. Name of the Device:

Bi-Directional Spiral & Epoxy Root Canal Cement System

3. Predicate Device Information:

1. AH-26® Root Canal Sealer (Pre-Amendment Device)
2. AH® PLUS® Root Canal Sealer, K# 960548, Dentsply International, York, PA

4. Device Description:

The subject device is an obturation system for filling straight and minimally curved canals. The bi-directional spiral and epoxy root canal cement, combined with a single point technique, creates a seal equivalent to lateral condensation and thermoplastic gutta percha. Contained in the kit are the following:

- 4 – Color Coded to ISO Size 25 Bi-Directional Spirals (1-21 mm length and 3-25 mm length)
- 7.5 gm – Epoxy Root Canal Cement Gel
- 8.0 gm – Powder (Epoxy Root Canal Cement)
- 1 Measuring Scoop

5. Intended Use:

The Bi-Directional Spiral & Epoxy Root Canal Cement System is indicated for permanent sealing of root canals following established endodontic procedures.

6. Comparison to Predicate Devices:

The Bi-Directional Spiral & Epoxy Root Canal Cement System and its predicates are all endodontic sealing cements containing two-component systems. The AH® PLUS® Root Canal Sealer is a two-paste system (Paste A is an epoxy resin paste and Paste B is amine-containing paste), whereas the AH-26® and subject device endodontic cements are based on a powder-liquid mix. All device' two-component systems react via an epoxide/amine reaction to cause setting, and thus used in conjunction with the same auxillary materials in the root canal (i.e., gutta percha points).

The subject device is a derivative of AH-26® (a well-know epoxy-resin cement that has been reported favorably in the dental literature for more than 45 years). The subject device is noneugenol-based (no incompatibility with subsequent resin restoration procedures). Both the AH-26® and subject device use silver as the primary radiopaquing agent and a bisphenol epoxy resin as the liquid/gel. The powder and liquid systems of both AH-26® and subject device filling cement allows the clinician to choose the viscosity of the material. The AH® PLUS® Root Canal Sealer and AH-26® Root Canal Sealer are compatable in setting time, flow, shrinkage and microleakage physical property values. The difference between the subject device and the AH-26® device is that subject device uses a bi-directional spiral technique that thoroughly coats the walls of the canal without letting any cement flow beyond the apex during the application process.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Bench Testing performed on the components (contained in the kit) of the Epoxy Root Canal Cement meet/exceed ADA Specification No.57 ISO 6876 (Dental Root Canal Filling Material) and (Endodontic Filling Materials) to include physical properties such as flow, film thickness, dimensional stability, solubility and disintegration. Bi-Directional Spiral (reverse spiral drill) dimensional inspections are checked against approved meeting all required specifications

8. Discussion of Clinical Tests Performed:

Biocompatibility literature supplied with this 510(k) submission along with Material Safety Data Sheets, has shown that components contained in the Bi-Directional Spiral & Epoxy Root Canal Cement System, as well as in the predicate devices, do not raise any new safety/biocompatibility concerns.

9. Conclusions:

The Bi-Directional Spiral & Epoxy Root Canal Cement System has the same intended use and similar technological characteristics as the predicate devices. Moreover, bench testing contained in this submission and clinical literature supplied demonstrate that any differences in their technological characteristics do not raise any new questions as to safety or effectiveness. Thus, the Bi-Directional Spiral & Epoxy Root Canal Cement System is substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2000

MDS
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent for MDS
MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K992727
Trade Name: The Bi-Directional Spiral & Epoxy Root Canal
Cement System
Regulatory Class: II
Product Code: KIF
Dated: August 11, 1999
Received: August 13, 1999

Dear Ms. Goldstein-Falk:

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.

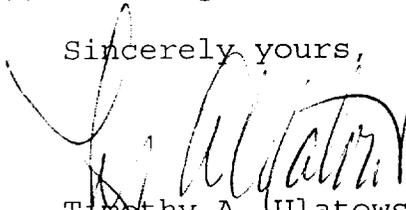
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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,



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

Enclosure

510(k) Number (if known): K992727

Device Name: The Bi-Directional Spiral & Epoxy Root Canal Cement System

Indications For Use:

The Bi-Directional Spiral & Epoxy Root Canal Cement System is indicated for permanent sealing of root canals following established endodontic procedures.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
 (Optional Format 1-2-96)

Susan P. Moran
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992727