K060075
P. 1 of 1

MAR 3 0 2006

Attachment I
510(k) Summary

Trade Name: **Foremost Fiber-Metal Post**

510(k) Sponsor: Foremost Dental, LLC
242 South Dean Street
Englewood, NJ 07631
FDA Registration # 2244812

Contact: George Wolfe, Product Development Manager

Device Generic Name: Root canal post

Device Classification: Class I

Classification Number: 21 CFR 872.3810

Product Code: 76 ELR

Predicate Devices:
The Foremost Fiber-Metal Post is substantially equivalent to several currently marketed root canal posts:

Product Name	510(k) #	510(k) Sponsor
Snowpost	K012354	Danville Materials, Inc.
everStick™ Post	K030820	Stick Tech, Ltd.
Fibiocore	K020431	Anthogyr

Indications for Use:
The Fiber-Metal Post is indicated for use as a root canal post. The post is cemented into the prepared root canal of a tooth to support a permanent restoration.

Product Description:
The Fiber-Metal Post consists of central core wires twisted around polymer bristles that extend radially from the core. The post will be available is several sizes (length and OD as measured over the fibers) and configurations based on bristle arrangement (straight or tapered).

Safety and Performance:
Performance testing for the Fiber-Metal Posts consisted of a cyclic loading test on teeth restored using the post. Both occlusal and lateral loading was evaluated. Unrestored, caries-free endodontically-treated teeth served as the control. The results of this test demonstrated that the Foremost Fiber-Metal Post, when used as directed in the device labeling, results in an acceptable fatigue cycle strength for the finished restoration.

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate devices, the Fiber-Metal Post has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2006

Foremost Dental, LLC
C/O Ms. Pamela Papineau
Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K060075
Trade/Device Name: Fiber-Metal Post
Regulation Number: 872.3810
Regulation Name: Root Canal Post
Regulatory Class: I
Product Code: ELR
Dated: January 3, 2006
Received: January 11, 2006

Dear Ms. Papineau:

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

510(k) Number (if known): K060075

Device Name: Fiber-Metal Post

Indications for Use:

The Fiber-Metal Post is indicated for use as a root canal post. The post is cemented into the prepared root canal of a tooth to support a permanent restoration.

Prescription Use X AND/OR Over-the -Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K060075