K032605

OCT - 8 2003

1 510(k) Summary

1.1 Date of Summary Preparation: June 26, 2003

1.2 Submitter/Contact Person: Jenny Sohn, Official Correspondent

TEL (718)-639-7460
FAX (718)-639-7408
Meta Dental Co.
41-19, 77th Street
Elmhurst, NY 11373

1.3 Trade Name/Common Name: Metapaste Calcium Hydroxide with Barium Sulfate Temporary Root Canal Filling

1.4 Common Name: Temporary Root Canal Sealer

1.5 Classification Name, Product Code, Class, Classification Reference:

Classification Name	Product Code	Class	21CFR §
Root Canal Filling Resin	KIF	II	872.3820

1.6 Standards/Special Controls:

ISO 6876 Dental root canal sealing materials.

1.7 Indications for Use:

Metapaste is a biocompatible root canal sealer used for the temporary filling of root canals after endodontic surgery. Metapaste can be used on its own and for vital pulpdectomies in decidious teeth.

Metapaste is intended for use by qualified healthcare personnel trained in its use.

1.8 Device Description:

Metapaste calcium hydroxide with Barium Sulfate is a device consisting of a temporary root canal sealer paste contained within a plastic syringe, packaged with disposable applicator tips and a plastic ring rotator for direction control of the tip. It is a device intended for use by qualified healthcare personnel trained in its use.

The Metapaste device is similar in design, materials and intended use to other 510(k) cleared devices which are in commercial distribution.

1.9 Substantially Equivalent Commercially Available Devices:

The Metapaste device is substantially equivalent to the predicate device described herein with respect to indications for use, device design, materials, and method of manufacture:

Pulpdent Calcium Hydroxide Preparation - K022734

Pulpdent Calcium Hydroxide Preparations – K944945 (Device Listing: Tempcanal-Temporary Calcium Hydroxide Root Canal Treatment 21 CFR § 872.3250)

The predicate devices are commercially available and a marketed Class II device indicated for use as a temporary root canal sealer.

1.10 Substantial Equivalence Comparison:

Metapaste is similar to commercially available device with respect to intended use, material, design and operational principles as follows:

	Metapaste	**Pulpdent Calcium Hydroxide Preparation (Tempcanal** K944945)	**Pulpdent Calcium Hydroxide Preparation** (K022734)
Labelling	Temporary root canal sealer	Temporary root canal sealer	Temporary or permanent root canal sealer
Intended Use	Metapaste is a biocompatible root canal sealer used for the temporary filling of root canals after endodontic surgery. Metapaste can be used on its own and for vital pulpdectomies in decidious teeth. Metapaste is intended for use by qualified healthcare personnel trained in its use.	A calcium hydroxide cavity liner material intended to be applied to the interior of a prepared cavity before insertion of restorative material, such as amalgam, to protect the pulp of a tooth.	A biocompatible polydimethylsiloxane based root canal sealer used for the temporary and permanent filling of root canals after endodontic surgery. Can be used on its own, in conjunction with Gutta Percha and for vital pulpdectomies in deciduous teeth.
Human Factors	Dispensed ready to use	Dispensed ready to use	Dispensed ready to use
Similar Physical Properties	ISO 6876 Fluidity, Working Time, Film Thickness, Radiopacity, Solubility & disintegration	ISO 6876 Fluidity, Working Time, Film Thickness, Radiopacity, Solubility & disintegration	ISO 6876 Fluidity, Working Time, Film Thickness, Radiopacity, Solubility & disintegration
Biocompatibility	Freedom from toxicity per ISO/TR 7405 Agar diffusion test Biocompatible per ISO 10993-11 Acute intervenous application	Freedom from toxicity per ISO/TR 7405 Agar diffusion test Biocompatible per ISO 10993-11 Acute intervenous application	Biocompatible

	Metapaste	Pulpdent Calcium Hydroxide Preparation (Tempcanal K944945)	Pulpdent Calcium Hydroxide Preparation (K022734)
Design, Construction, Components	Premixed paste, packaged in plastic syringe ready to be dispensed through disposable tips into root canal	Premixed paste, packaged in plastic syringe ready to be dispensed through disposable tips into root canal	Premixed paste, packaged in plastic syringe ready to be dispensed through disposable tips into root canal

1.11 Indications and Contraindications:

Relative indications and contraindications for Metapaste and commercially available devices for similar intended uses are the same.

1.12 Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Meta Biomed Co., Ltd concludes that the new device, Metapaste root canal sealer, is safe, effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 8 2003

Meta Biomed Company Limited Institute
C/O Mr. Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue, SE
Grand Rapids, Michigan 49548

Re: K032605
Trade/Device Name: Metapaste Calcium Hydroxide with Barium Sulfate Root Canal Filling
Regulation Number: 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: September 22, 2003
Received: September 23, 2003

Dear Mr. Devine:

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.

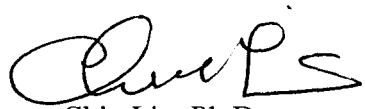
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032605

Indications for Use

510(k) Number:

Device Name : Metapaste Calcium Hydroxide with Barium Sulfate Root Canal Filling

Indications for Use:

For use, as a temporary root canal filling after endodontic surgery. Metapaste can be used on its own and for vital pulpdectomies in decidious teeth.

Metapaste is intended for use by qualified healthcare personnel trained in its use.

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K032605

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)