K042769

# 1 510(k) Summary

NOV 2 4 2004

**1.1 Date of Summary Preparation:** March 24, 2004

**1.2 Manufacturers Contact Person:** Jenny Sohn, Official Correspondent

TEL (718)-639-7460
FAX (718)-639-7408
Meta Dental Co.
82-06 Grand Avenue
Elmhurst, NY 11373

**1.3 Name**

**Trade Name:** Adseal
**Common Name:** Root Canal Sealer

**1.4 Classification Name, Product Code, Class, Classification Reference:**

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

**1.5 Standards/Special Controls:**

ISO 6876 Dental root canal sealing materials.

**1.6 Indications for Use:**

Adseal is a biocompatible root canal sealer for permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

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

**1.7 Device Description:**

Adseal root canal sealer is a two component paste:paste device based upon epoxy-amine resin chemistry. This sealer is easy to mix and adapts closely to the walls of the prepared root canal and provides outstanding long-term dimensional stability with minimal shrinkage upon setting.

The device consists of tow components, the epoxy resin paste (Paste A) and the amine-containing paste (Paste B); portions of which are mixed prior to insertion into the root canal. This two component system reacts via an epoxide-amine chemical reaction to cause setting. It may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).

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II

Paste A and Paste B are contained, separately, with the chambers of a two component plastic syringe, packaged with a disposable applicator.

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

## 1.8 Substantially Equivalent Commercially Available Devices:

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

Bi-Directional Spiral & Epoxy Root Canal Cement System K992727
Dentsply AH Plus Root Canal Sealer K960548
Dentsply AH 26 Root Canal Sealer (Pre- Amendment Device)

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

## 1.9 Substantial Equivalence Comparison:

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

| | Adseal | MDS Bi-Directional Spiral & Epoxy Root Canal Cement System | Dentsply AH 26 | Dentsply AH Plus |
|---|---|---|---|---|
| **Labelling** | Permanent root canal sealer | Permanent root canal sealer | Permanent root canal sealer | Permanent root canal sealer |
| **Intended Use** | For permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).<br><br>Intended for use by qualified healthcare personnel trained in its use. | For permanent sealing of root canals following established endodontic procedures.<br><br>Intended for use by qualified healthcare personnel trained in its use. | For permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).<br><br>Intended for use by qualified healthcare personnel trained in its use. | For permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points).<br><br>Intended for use by qualified healthcare personnel trained in its use. |
| **Human Factors** | Mixed, two part system | Mixed, two part system | Mixed, two part system | Mixed, two part system |
| **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 | ISO 6876 Fluidity, Working Time, Film Thickness, Radiopacity, Solubility & disintegration |

| | Adseal | MDS Bi-Directional Spiral & Epoxy Root Canal Cement System | Dentsply AH 26 | Dentsply AH Plus |
|---|---|---|---|---|
| **Biocompatibility** | Freedom from toxicity per ISO/TR 7405 Agar diffusion test<br><br>Biocompatible per ISO 10993-11 Acute intervenous application | Biocompatible | Biocompatible | Biocompatible |
| **Design, Construction, Components** | Premixed, two part paste, packaged in two component plastic syringe ready to be dispensed and mixed | Premixed, two part powder/liquid-gel, packaged and ready to be dispensed and mixed | Premixed, two part powder/liquid-gel, packaged in a bottle and tube ready to be dispensed and mixed | Premixed, two part paste, packaged in two individual tubes ready to be dispensed and mixed |

## 1.10 Indications and Contraindications:

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

## 1.11 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, Adseal 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

NOV 2 4 2004

Meta Biomed Company Limited
C/O Mr. Ned Devine
Responsible Third Party Official
Entela, Incorporated
3033 Madison Avenue SE
Grand Rapids, Michigan 49548-1289

Re: K042769
Trade/Device Name: Adseal Root Canal Filling
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: November 10, 2004
Received: November 12, 2004

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.

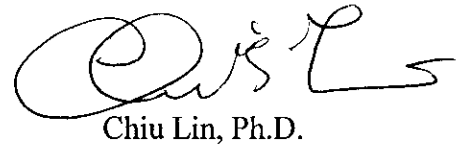
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

# Indications for Use

**510(k) Number (if known):** K042769

**Device Name :** Adseal Root Canal Filling

**Indications for Use:**

Adseal is a biocompatible root canal sealer for permanent sealing of root canals following established endodontic procedures and may be used in conjunction with the auxiliary materials in the root canal (i.e. gutta percha points)

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

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K042769