

1.8 Substantially Equivalent Commercially Available Devices:

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

Vitapex Pre-Loaded Dental Syringe ~ (K973667)

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

1.9 Substantial Equivalence Comparison:

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

	Metapex	Vitapex Pre-Loaded Dental Syringe
Labelling	Temporary or permanent root canal sealer	Temporary or permanent root canal sealer
Intended Use	<p>For use, as a temporary or permanent root canal sealer, to stimulate healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.</p> <p>Intended for use by qualified healthcare personnel trained in its use.</p>	<p>For use, as a temporary or permanent root canal sealer, to stimulate healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.</p> <p>Intended for use by qualified healthcare personnel trained in its use.</p>
Human Factors	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

	Metapex	Vitapex Pre-Loaded Dental Syringe
Biocompatibility	Freedom from toxicity per ISO/TR 7405 Agar diffusion test Biocompatible per ISO 10993-11 Acute intravenous application	Freedom from toxicity per ISO/TR 7405 Agar diffusion test Biocompatible per ISO 10993-11 Acute intravenous application
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

1.10 Indications and Contraindications:

Relative indications and contraindications for Metapex 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, Metapex root canal sealer, is safe, effective and substantially equivalent to the predicate device as described herein.



OCT - 7 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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: K032603

Trade/Device Name: Metapex Calcium Hydroxide with Lodoform 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 Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

1

510(k) Number:

Device Name : Metapex Calcium Hydroxide with Iodoform Root Canal Filling

Indications for Use:

Metapex calcium hydroxide with iodoform is a biocompatible temporary or permanent root canal sealer, for use to stimulate healing process due to the mixture of calcium hydroxide and iodoform and the induction effect of these two ingredients. Used to promote healing effects and to help prevent bacterial contamination of the canal, as the two ingredients improve the induction effect for hard tissue induction and deposition. To be used as a medicament for the treatment of infected root canals, and as a permanent, low volume additive to the filling process of a treated root canal to assist in the induction and deposition of hard tissue to make the healing process more rapid and complete. For use in the treatment of infected root canals, or following pulpectomy, or for apexogenesis or apexification, and/or for the tip filling of prepared, treated root canals at the time of final filling with gutta-percha.

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



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

510(k) Number: K032603

(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