APR 09 2014

K133716

510(k) Summary

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: ___04/09/2014___

1. Applicant / Submitter:

KM Corporation
727 , Seoun-ro, Miyang-myeon, Anseong-si,
Gyeonggi-do, 456-843, Republic of Korea

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2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110,
Fullerton, CA 92831
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	TRC-Paste
Common Name:	Temporary Root Canal Filling Material
Classification Name:	Root Canal Filling Resin
Classification:	Class II, 21 CFR 872.3820
Classification Product Code:	KIF

4. Predicate Device:

Metapex by Meta Dental Co. (K032603)

5. Device Description:

TRC-Paste is an immediately available pre-mixed root canal filling material based on Calcium hydroxide and Polypropylene Glycol 2000.
This pre-mixed temporary filling material maintains a constant flow, which makes it easy to inject into the canal. Depending on apicoectomy or infected root canal therapies, it can be

used as a temporary root canal filling material. The device is contained in a plastic syringe and the system includes a plunger, disposable tips, a rubber, a protective cap, an indo stop and a holder for direction control of the tip.

6. Intended Use:

TRC-Paste is a biocompatible temporary root canal sealer for use in the treatment of root canals, or following pulpectomy, or for apexegenesis or apexification, and for the tip filling of prepared, treated root canals at the time of final filling with gutta- percha.

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results met the preset test criteria.

- ISO 6876 - Radiopacity, Flowability
- ISO 10993-5 - Cytotoxicity
- ISO 10993-6 - Implantation
- ISO 10993-11 - Short-term systemic toxicity(Oral)
- ASTM F1980-07 – Shelf life test
- Other bench testing - Appearance, volume, and packaging tests

8. Substantial Equivalence

The TRC-paste is substantially equivalent to the predicate device described herein with respect to intended use, device design, main raw material, accessory components, and delivery method.
The difference is the compositions of some additives; however, the biocompatibility and the performance testing results show that this difference does not raise issues in safety and effectiveness.

9. Conclusion:

Based on the testing results, KM Corporation concludes that the TRC-Paste is substantially equivalent to predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

KM Corporation
C/O Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton, CA 92833

Re: K133716
Trade/Device Name: TRC-Paste
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: January 13, 2014
Received: January 15, 2014

Dear Ms. Chung:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133716

Device Name
TRC-Paste

Indications for Use *(Describe)*
TRC-Paste is a biocompatible temporary root canal sealer for use in the treatment of root canals, or following pulpectomy, or for apexegenesis or apexification, and for the tip filling of prepared, treated root canals at the time of final filling with gutta- percha.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
2014.04.09 11:03:10 -04'00'