K132123

MAR 2 0 2014

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: ___03/11/2014___

1. Submission Applicant:

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Contract Person: Kweonmyeong Jang / Quality Management Department

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-Pex Radic-Sealer
Common Name:	Root Canal Filling Material Root Canal Sealing 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)
Adseal by Meta Dental Co. (K042769)
AH Plus by Dentsply DeTrey GmbH (K960548)

5. Device Description:

TRC-Pex

TRC-Pex is an immediately available pre-mixed root canal filling material based on Calcium Hydroxide and Iodoform. This pre-mixed temporary filling material maintains a constant flow, which makes it easy to inject into the canal. Depending on apicoectomy or 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.

Radic-Sealer

Radic-Sealer is a root canal sealing & filling material based on epoxy-amine resin. Radic-Sealer is contained in a dual syringe which makes it easy to mix and inject. It makes permanent obturation of root canals using adhesion properties between root canal walls and the root canal filling materials. The base and catalyst are contained separately in the chambers of two separate plastic syringes. The product consists of a mixing tip with a mixing joint, a protective cap, a mixing pad, and a plunger.

6. Intended Use:

TRC-Pex

The TRC-Pex is a temporary root canal sealer for use in the treatment of root canals, following a pulpectomy or for apexegenesis or apexification.

Radic-Sealer

The Radic-Sealer is a 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). The Radic-Sealer is intended for use by qualified healthcare personnel trained in its use.

7. Substantial Equivalence

The TRC-Pex and the Radic-Sealer are substantially equivalent to the predicate devices

with respect to intended use, accessory components, delivery method, and physical properties. The difference is the compositions of raw materials; however, the biocompatibility and the performance testing results show that this difference does not raise issues in safety and effectiveness.

8. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards.

- ISO 6876 - Radiopacity, Liquidity, Setting time, Solubility test, Film Thickness, Flowability
- ISO 10993-5 - Cytotoxicity
- ISO 10993-10 - Oral Mucous Irritation & Sensitization
- ISO 10993-11 - Short-term systemic toxicity (Oral)
- Other bench testing – Shelf life, appearance, volume/weight spec, and packaging tests

Performance testing that confirmed to the protocols and recommended values described in ISO 6876 was performed. We believe that the performance data provided demonstrate that TRC-Pex and Radic-Sealer are substantially equivalent to the predicates in design, principle of performance, and technology.

Biocompatibility data were provided to demonstrate substantial equivalence to the predicate devices. Side-by-Side cytotoxicity testing was performed that compared the TRC-Pex and a predicate device, and the test results showed that they have similar biocompatibility properties.

The bench and biocompatibility tests provided evidence that the chemical and physical properties of TRC-Pex and Radic-Sealer are substantially equivalent to the predicate devices.

9. Conclusion:

Based on the testing results, KM Corporation concludes that the TRC-Pex and the Radic-Sealer are substantially equivalent to predicate device in safety, effectiveness and performance.

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

March 20, 2014

KM Corporation
C/O Ms. Priscilla Chung
LK Consulting Group USA, Inc.
2651 E Chapman Ave Ste 110
Fullerton, CA 92831

Re: K132123
Trade/Device Name: TRC-Pex, Radic-sealer
Regulation Number: 21 CFR
Regulation Name: Root Canal Filling Material, Root Canal Sealing Material
Regulatory Class: Class II
Product Code: KIF
Dated: February 11, 2014
Received: February 14, 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" (21 CFR 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,

Erin I. Keith -S

Erin I. Keith
Acting 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)*
K132123

Device Name
TRC-Pex, Radic-Sealer

Indications for Use *(Describe)*

TRC-Pex

The TRC-Pex is a temporary root canal sealer for use in the treatment of root canals, following a pulpectomy or for apexegenesis or apexification.

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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)*

Susan Runner DDS, MA Mary S. Runner -S
2014.03.18 13:46:18 -04'00'

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