K140846

JUL 25 2014

ESSENTIAL DENTAL SYSTEMS

CE APPROVED PRODUCTS

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Section 5 - 510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Submitter's Identification:**

Essential Dental Systems
89 Leuning Street
South Hackensack, NJ 07606

Date Summary Prepared: July 1, 2014

Contact: Mr. Jeffrey Wan
Contact Email: jwan@edsdental.com
Contact Phone #: 201-487-9090 ext. 118
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2. **Name of the Device:**

Trade name: EDS Combo-Rinse
Common name: Cleanser, Root Canal
CFR Number: N/A
Device class: Unclassified
Product Code: KJJ

3. **Predicate Device Information:**

1. QMix™ 2in1 Endodontic Irrigating Solution, Dentsply International, K103244
2. Etch-37™, Bisco Inc., K101485
3. MicroPrime B, Danville Engineering Inc., K953504

4. **Device Description:**

EDS Combo-Rinse is an aqueous solution for use during the irrigation phase of endodontic root canal preparation procedures. The device has a dual purpose of flushing out any loosened debris and removing the smear layer produced from root canal instrumentation.

5. **Intended Use:**

EDS Combo-Rinse is a device that cleanses root canal systems by irrigating root canals.

6. **Comparison to Predicate Devices:**

A comparison of EDS Combo-Rinse and the 510(k) cleared QMix™ 2in1 Endodontic Irrigating Solution indicates the following similarities and differences to the device which received 510(k) clearance:

> EDS Combo-Rinse is similar to the predicate device QMix™ 2in1 Endodontic Irrigating Solution in that they are both aqueous solutions intended as endodontic irrigants to clean the root canal system and remove the smear layer. Two active ingredients contained in the proposed device are also found in the predicate device.
>
> EDS Combo-Rinse is different from the predicate device QMix™ 2in1 Endodontic Irrigating Solution in that the proposed device does not disinfect the root canal. The proposed device also differs from the predicate device in the secondary components in their respective formulations.

All of the components found in the predicate devices have been used in legally marketed devices and were found safe for dental use. We believe that prior use of components in legally marketed devices, the performance and biocompatibility data provided support the safety and effectiveness of EDS Combo-Rinse for the indicated uses.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:**

Biocompatibility testing and smear layer removal testing was conducted to determine equivalence of EDS Combo-Rinse to the predicate device QMix™ 2in1 Endodontic Irrigating Solution.

> The results of five biocompatibility tests according to ISO 10993 demonstrate equivalence in safety to the predicate device.
>
> The smear layer removal testing performance data demonstrates equivalence in performance to the predicate device.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

9. Conclusions:

EDS Combo-Rinse is substantially equivalent to the currently cleared and marketed QMix™ 2in1 Endodontic Irrigating Solution.

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

July 25, 2014

Essential Dental Systems, Inc.
Mr. Jeffrey Wan
Research and Development Manager
89 Leuning Street
South Hackensack, NJ 07606

Re: K140846
Trade/Device Name: EDS Combo-Rinse
Product Code: KJJ
Regulatory class: unclassified
Dated: July 1, 2014
Received: July 1, 2014

Dear Mr. Wan:

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.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use

510(k) Number (if known): K140846

Device Name: EDS Combo-Rinse

Indications for Use:

EDS Combo-Rinse is intended to cleanse root canal systems by irrigating root canals.

Prescription Use X **(Per 21 CFR 801 Subpart D)**	**OR**	**Over the Counter Use** ____ **(Per 21 CFR 807 Subpart C)**

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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