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

February 1, 2016

Pac-dent International, Inc.
Mr. Wenying Zhu
Materials Engineer
670 Endeavor Circle
Brea, California 92821

Re: K153528
Trade/Device Name: PacEndo™ EDTA
Regulation Number: 21 CFR
Regulatory Class: Unclassified
Product Code: KJJ
Dated: December 2, 2015
Received: December 9, 2015

Dear Mr. Zhu:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

for 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

Pac-Dent International, Inc.

670 Endeavor Circle
Brea, CA 92821 • U.S.A.
T 909.839.0888
F 909.839.0881
www.pac-dent.com

Section III

Indications for Use Statement

510(k) Number (if known): K153528

Device Name: PacEndo™ EDTA

Indications for Use:

PacEndo™ EDTA is intended to facilitate removal of dentinal debris from the walls of root canals prior to obturation.

Prescription Use X OR Over-The-Counter Use _____

Pac-Dent International, Inc.
670 Endeavor Circle
Brea, CA 92821 • U.S.A.
T 909.839.0888
F 909.839.0881
www.pac-dent.com

510(k) Summary

510(k) Number: K153528

Submitter:
Pac-Dent International, Inc.
670 Endeavor Circle
Brea, CA 92821

Contact Person:
Wenying Zhu
Materials Engineer
909-839-0888 ext.111

Date Summary Prepared:
December 2015

Device Name

Trade Name: PacEndo™ EDTA
Common Name: Endodontic Cleanser
Device Classification: Unclassified
Classification Product Code: KJJ
Classification Name: Cleanser, Root Canal

Predicate Device

EDTA Plus (K072555)

Description of Device

PacEndo™ EDTA is an EDTA solution in water with surfactant to lower surface tension. The solution is a root canal cleanser for use in endodontic procedures to remove the smear layer produced from root canal instrumentation.

Indications for Use

PacEndo™ EDTA is intended to facilitate removal of dentinal debris from the walls of root canals prior to obturation.

670 Endeavor Circle
Brea, CA 92821 • U.S.A.
T 909.839.0888
F 909.839.0881
www.pac-dent.com

Comparison of Technological Characteristics

Descriptive Information	**Subject Device** PacEndo™ EDTA	**Predicate Device** EDTA Plus (K072555)	**Summary**
Indications for Use	PacEndo™ EDTA is intended to facilitate removal of dentinal debris from the walls of root canals prior to obturation.	EDTA Plus is a root canal cleanser designed to facilitate removal of dentinal debris from the walls of root canals prior to obturation.	The indications for use of the subjective and predicate devices are the same.
Composition of Materials	EDTA Buffer Surfactant	EDTA Buffer Surfactant	The composition of subject and predicate devices is different. However, the functions of the ingredients are the same. The difference between the composition of the subject and predicate devices doesn't affect the substantial equivalent of the subject and predicate devices.
Performance	Appearance: clear liquid pH: 7.56	Appearance: light peach color liquid pH: 7.55	The appearances of the subject and predicate devices are not the same. However, it doesn't affect the substantial equivalent of the subject and predicate devices.

Based on the above comparisons, Pac-Dent concludes that the subject device is substantially

670 Endeavor Circle
Brea, CA 92821 • U.S.A.
T 909.839.0888
F 909.839.0881
www.pac-dent.com

equivalent in intended use, composition and performance to the predicate device.

Non-Clinical Tests

Surface tension test using contact angle measurement was performed in comparison to the predicate device.

A biocompatibility assessment and risk analysis were conducted and the results demonstrated that no biocompatibility testing was needed to demonstrate biocompatibility of the device for the intended use.

Clinical Performance Test

No clinical testing was provided.

Summary of Non-Clinical and Clinical Performance Testing

The subject device was found to have similar surface tension compared to the predicate device and can be used as intended.

Conclusion

In summary, non-clinical performance testing demonstrates that PacEndo™ EDTA is substantially equivalent to the identified predicate product for its intended use.