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, 2016

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

Re: K160577
Trade/Device Name: PacEndo™ Chlorhexidine
Regulation Number: n/a
Regulation Name: n/a
Regulatory Class: Unclassified
Product Code: KJJ
Dated: June 8, 2016
Received: June 15, 2016

Dear Ms. 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" (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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160577

Device Name
PacEndo Chlorhexidine

Indications for Use *(Describe)*
PacEndo Chlorhexidine is intended to irrigate and cleanse root canal systems after endodontic instrumentation.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section IV

510(k) Summary

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:
Feb 19 2016

Device Name

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

Predicate Device

CHX and CHX-Plus™ (K112250)

Description of Device

PacEndo™ Chlorhexidine is a 2% Chlorhexidine Gluconate solution in water with surfactant to lower surface tension. The solution is root canal cleanser for use in endodontic procedures.

Indications for Use

PacEndo™ Chlorhexidine is intended to irrigate and cleanse root canal systems after endodontic instrumentation.

Comparison of Technological Characteristics

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Descriptive Information	Subject Device PacEndo™ Chlorhexidine	Predicate Device CHX and CHX-Plus™ (K112250)	Summary
Indications for Use	PacEndo™ Chlorhexidine is intended to irrigate and cleanse root canal systems after endodontic instrumentation.	CHX and CHX-Plus™ are used as a final endodontic rinse after instrumentation to irrigate and cleanse the root canal system for long lasting cleansing	Although the wording is not identical, both devices are used for endodontic procedures to irrigate and cleanse the root canal.
Composition of Materials	Chlorhexidine Gluconate Surfactant	Chlorhexidine Gluconate Surfactant Colorant	The functions of the ingredients in subject and predicate devices are the same.
Performance	Appearance: clear to light yellow liquid pH Testing Surface Contact Angle Testing	Appearance: clear to light blue liquid pH Testing Surface Contact Angle Testing	The difference between the appearances of the subject and predicate devices 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 equivalent in intended use, composition and performance to the predicate device.

Non-Clinical Tests

Comparative testing was done to the noted predicate device for both pH and surface contact angle. The results of the comparative testing demonstrate that the subject device performs as well as the noted predicate in the surface contact angle testing and that both devices share similar pH values.

Conclusion

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