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

November 10, 2015

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

Re: K151852
Trade/Device Name: PacEndo™ Sodium Hypochlorite
Regulatory Class: Unclassified
Product Code: KJJ
Dated: September 28, 2015
Received: October 6, 2015

Dear Wenying 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.

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Section III

Indications for Use Statement

510(k) Number (if known): K151852

Device Name: PacEndo™ Sodium Hypochlorite

Indications for Use:

PacEndo™ Sodium Hypochlorite is intended to irrigate, cleanse, and debride root canal systems. It is also intended to provide irrigation during root canal instrumentation.

Prescription Use X OR Over-The-Counter Use _____

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Section IV

510(k) Summary K151852

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:

November 9th 2015

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

Predicate Device
3% and 6% Sodium Hypochlorite with wetting agents marketed as Chlor-XTRA™ (K082470)

Description of Device
PacEndo™ Sodium Hypochlorite is a Sodium Hypochlorite solution in water with surfactant to lower surface tension. The solution is root canal cleanser for use in endodontic procedures.

Indications for Use
PacEndo™ Sodium Hypochlorite is intended to irrigate, cleanse, and debride root canal systems. It is also intended to provide irrigation during root canal instrumentation.

Comparison of Technological Characteristics

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Descriptive Information	Subject Device PacEndo™ Sodium Hypochlorite	Predicate Device 3% and 6% Sodium Hypochlorite with wetting agents marketed as Chlor-XTRA™ (K082470)
Indications for Use	PacEndo™ Sodium Hypochlorite is intended to irrigate, cleanse, and debride root canal systems. It is also intended to provide irrigation during root canal instrumentation.	Sodium Hypochlorite 3% and 6% and Sodium Hypochlorite 6% with wetting agents to lower surface tension marketed as Chlor-XTRA are solutions used for debridement and the instrumentation of root canal. Sodium Hypochlorite 3% and 6% and Chlor-XTRA 6% are Sodium Hypochlorite in water.
Composition of Materials	Sodium Hypochlorite Surfactant	Sodium Hypochlorite Surfactant Wetting agent
Performance	Appearance: clear to light yellow liquid pH: 12.11 % Active Chlorine (w/w): 4.6%	Appearance: clear to light yellow liquid pH: 12.02 % Active Chlorine (w/w): 5.3%

The indications for use statement for the subject device is similar to the predicate device, but introduces the use of the device more in details, which is to irrigate, cleanse, and debride root canal systems. The indications for use doesn't change the intended use of the product.

Non-Clinical Tests

Surface tension test using contact angle measurement was performed in comparison to the predicate device.
Justification based on risk analysis, for not doing biocompatibility testing was provided.

Clinical Performance Test

No clinical testing was provided.

Summary of Non-Clinical and Clinical Performance Testing

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

Conclusion

In summary, this submission demonstrates that PacEndo™ Sodium Hypochlorite is substantially equivalent to the identified predicate product for its intended use.