DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Nanning Vv Dental Co., Ltd.
Liang Chaojun
Vice General Manager
4th Floor,north Bld. No.1 , Zhengxin Tech Zone, No. 2,
Gaoxin 7 Rd.
Nan Ning, 530007 CN

November 21, 2017

Re: K163414
Trade/Device Name: Ultrasonic Scaler
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: elc
Dated: October 25, 2017
Received: October 27, 2017

Dear Liang Chaojun:

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,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163414

Device Name

Ultrasonic Scaler

Indications for Use *(Describe)*

The ultrasonic scaler is intended to:
1. Remove supra and sub gingival calculus deposits and stain from the teeth;
2.Carry out periodontal pocket lavage with simultaneous ultrasonic tip movement;
3.Clean and irrigate root canals

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.

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K163414
510(k) SUMMARY

(As Required by 21 CFR 807.92)

1. Date Prepared

   October 2nd, 2017

2. Submitter;s Information

Company Name:	NANNING VV DENTAL CO., LTD.
Company Address:	4th floor,North Bld. No.1 , Zhengxin Tech Zone, No. 2, Gaoxin 7 Rd., Nanning, China 530007
Fax:	0086-771-580-1312

3. Device Information

Trade Name:	Ultrasonic Scaler
Models:	VET-W3, VST-W3, VET-1 and VST-1
Product Code:	ELC
Regulation Number:	21 CFR 872.4850
Device Class:	Class II

4. Identification of Predicate Devices

   Predicate I

Manufacturer:	Nanning Baolai Medical Instruments Co., Ltd.
Trade Name:	Ultrasonic scaler P7
Product Code:	ELC
Classification Name:	Ultrasonic Scaler
Regulation Number :	21 CFR 872.4850
FDA 510 (k) #:	K140233

5. Description of the Device

   The Ultrasonic scaler employs piezoelectric technology to produce a steady power. It is composed of a control unit housing a generator that produces piezo-electric vibrations. The working instrument for the ultrasonic scaler is the handpiece, which is connected to the control unit via a handpiece cord. A scaling tip specific to a particular procedure is attached to the end of the handpiece. The ultrasonic scaler models VET-W3 and VST-W3 connect to an external water supply and delivers water via connected handpiece.

Ultrasonic scaler consists of main generator, VE and VS handpiece, optional scaler tips (G series, P series, E series), power adapter and foot switch;
The main part is as follows:
1. Power adapter: DC 24V, input frequency: 3-20W
2. Main engine: The main engine is the major part of the circuit control, including ultrasonic pulse circuit, modulator circuit and oscillatory circuit. It is used for converting the ultrasonic oscillatory signal to ultrasonic mechanical oscillatory signal by magnifying and improving the vibrating frequency.
3. Handpiece: It mainly converts the signal from circuit,which will drive the ultrasonic scaler tips vibrating.
4. Scaler tip: The scaler tip is used to remove the calculus and plague by vibrating on the teeth surface.

6. Indications For Use

The ultrasonic scaler is intended to:
1.Remove supra and sub gingival calculus deposits and stain from the teeth; 2.Carry out periodontal pocket lavage with simultaneous ultrasonic tip movement; 3.Clean and irrigate root canals

7. Technological Characteristics

The ultrasonic scaler is powered by the piezoelectric technology, which is also employed by the predicate device. The electric power is transduced into high- frequency vibration via an ultrasonic transducer. The proposed ultrasonic scaler connects to an external water supply and delivers water via connected handpiece.

8. Substantial Equivalence Table

Items	**K163414 Proposed Device**	**K140233 Predicate Device Ultrasonic scaler P7**
Indications For Use	The ultrasonic scaler is intended to: 1.Remove supra and sub gingival calculus deposits and stain from the teeth;	The ultrasonic scaler is intended to: 1.Remove supra and sub gingival calculus deposits and stain from the teeth;
	2. Carry out periodontal pocket lavage with simultaneous ultrasonic tip movement; 3. Clean and irrigate root canals.	2. Carry out periodontal pocket lavage with simultaneous ultrasonic tip movement; 3. Clean and irrigate root canals.

Operation Controls	Sterilization: Handpiece: autoclaved under high temperature 135℃/pressure 0.22MPa. Scaler tip : autoclaved under high temperature and high pressure	Sterilization: Handpiece: autoclaved under high temperature 135℃/pressure 0.22MPa. Scaler tip: autoclaved under high temperature and pressure.
Display Modes	Corresponding signal of external display driver circuit lights up corresponding LED.	Corresponding signal of external display driver circuit lights up corresponding LED.
Measurement Items	Remove calculus or plaque on surface of teeth in oral cavity, cleaning and irrigation of root canals.	Remove calculus or plaque on surface of teeth in oral cavity, cleaning and irrigation of root canals.
Power Supply	input voltage：30VDC 50HZ	input voltage ： 24VDC 1.5A 50HZ
	output power：3-20W	output power：3-20W
Operating conditions	temperature：5℃～40℃	temperature：5℃～40℃
	relative humidity：30%～80%	relative humidity ： 30%～ 80%
	pressure：50kPa～106kPa	pressure：50kPa～106kPa
Storage conditions	temperature：-10℃~+50℃	temperature：-10℃~+50℃
	relative humidity≦80%	relative humidity≦80%
	pressure50kPa～106kPa	pressure50kPa～106kPa
Handpiece of ultrasonic scaler	Working principle: Piezoelectric effect, the ultrasonic vibration signal is converted to ultrasonic mechanical vibration signal.	Working principle: Piezoelectric effect, the ultrasonic vibration signal is converted to ultrasonic mechanical vibration signal.
Tips of ultrasonic scaler	Mechanical vibration transmitted from the handpiece is converted to the vibration of the scaler tip, then removes calculus or plaque from the teeth.	Mechanical vibration transmitted from the handpiece is converted to the vibration of the scaler tip, then removes calculus or plaque from the teeth.
Electrical Safety	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2
performance	IEC 61205	IEC 61205

Biocompati-bility	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10
Software Level of Concern	Moderate	Moderate

The proposed device has same intended use, similar product design, same sterilization condition, safety standards as the predicate device. The slight difference is the power supply, the input voltage of proposed device is 30V DC , the input voltage of predicate device is 15V DC, both of them could meet the electricity safety standard IEC 60601-1, the difference does not affect the substantial equivalence in effectiveness and safety.

Non-clinical Testing:
The following bench testing was conducted in order to support substantial equivalence of the proposed device:

- IEC 60601-1:2006+A1:2012 medical electrical equipment -- part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2:2007 medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
- IEC 61205:2001 Ultrasonics-Dental descaler systems-Measurement and declaration of the output characteristics.
- ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization.

Clinical Testing:
Clinical evaluation is not applicable for the proposed device.

9. Conclusion [21 CFR 807.92(b)(3)]

The VET-W3, VST-W3,VET-1 and VST-1 ultrasonic scaler have the same intended use, similar product design, same sterilization conditions and the same technological characteristics as the predicate device. Nonclinical testing further supports the substantial equivalence of the proposed device to its predicate device. Therefore, the proposed device is substantially equivalent to its predicate device.