July 2, 2024

Shenzhen Micro Electric Intelligence Co., Ltd.
Fengmeng Han
General Manager
301, Building A5, No. 13 Baonan Road, Longgang Community
Longgang District
Shenzhen, Guangdong 518100
CHINA

Re: K240707
Trade/Device Name: Ultrasonic Scaler (WD-JY-B002,WD-JY-W001,WD-JY-R003,WD-JY-G004,WD-JY-B003,WD-JY-C006,WD-JY-M0014, WD-JY-N0015,WD-JY-N0016,WD-JY-N0017,WD-JY-E007, WD-JY-F008,WD-JY-A005,WD-JY-H009,WD-JY-I0011, WD-JY-K0012,WD-JY-K0013,WD-JY-K0014, WD-JY-L0013,WD-JY-L0014,WD-JY-L0015, WD-JY-L0016,WD-JY-L0017)
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: June 3, 2024
Received: June 3, 2024

Dear Fengmeng Han:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240707

Device Name
Ultrasonic Scaler (WD-JY-B002,WD-JY-W001,WD-JY-R003,WD-JY-G004,WD-JY-B003,WD-JY-C006,WD-JY-M0014, WD-JY-N0015,WD-JY-N0016,WD-JY-N0017,WD-JY-E007, WD-JY-F008,WD-JY-A005,WD-JY-H009,WD-JY-I0011, WD-JY-K0012,WD-JY-K0013,WD-JY-K0014, WD-JY-L0013,WD-JY-L0014,WD-JY-L0015, WD-JY-L0016,WD-JY-L0017)

Indications for Use *(Describe)*
Ultrasonic Scaler is used to remove dental plaque from teeth and remove stains on teeth during dental cleaning.

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.

K240707_510(k) summary

I Submitter

Device Submitter

Shenzhen Micro Electric Intelligence Co., Ltd.

301, Building A5,No. 13 Baonan Road, Longgang Community, Longgang District, Shenzhen

Contact Person

FANGMENG HAN

General Manager

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Prepare Date: July 1, 2024

II Device

Trade Name of Device:	Ultrasonic Scaler
Common Name	Ultrasonic Scaler
Regulation Number:	21 CFR 872.4850
Regulation Name:	Scaler, Ultrasonic
Regulatory Class:	II
Product code:	ELC
Review Panel:	Dental

III Predicate Devices

510(k) Number	K163414
Device Name	Ultrasonic scaler
Manufacturer	NANNING VV DENTAL CO., LTD.
Regulation Number:	21 CFR 872.4850
Regulatory Class:	II
Product code:	ELC
Review Panel:	Dental

IV Device description

A device intended for use during dental cleaning and periodontal (gum) therapy to remove adherent plaque and food debris from the teeth to reduce tooth decay, potential stains in the gingival groove, the back of the tooth and the tooth and associated gingival line.

The electronic oscillation circuit generates ultrasonic frequency electric pulse wave, which is amplified to a certain intensity and conveyed to the transducer. The electrical energy is

converted into mechanical energy, and the working head tool is stimulated to produce vibration of the same frequency, so as to achieve the purpose of crushing calculus and loosening tartar.

V Indications for use

Ultrasonic Scaler is used to remove dental plaque from teeth and remove stains on teeth during dental cleaning.

VI Comparison of technological characteristics with the predicate devices

The Ultrasonic Scaler has the same intended use, technology, design and performance specifications are either identical or substantially equivalent to existing legally marketed predicate devices. The differences between the Ultrasonic Scaler and predicate devices do not alter suitability of the proposed device for its intended use.

Item	Proposed Device	Predicate Device (K163414)	Comparison
Manufacturer	Shenzhen Micro Electric Intelligence Co., Ltd.	NANNING VV DENTAL CO., LTD.	/
Regulation No.	21 CFR 872.4850	21 CFR 872.4850	Identical
Class	II	II	Identical
Product Code	ELC	ELC	Identical
Indication for use	Ultrasonic Scaler is used to remove dental plaque from teeth and remove stains on teeth during dental cleaning.	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	Identical
Operation Controls	Cleaning and disinfection method of tooth cleaning tip: after each use, scald	Scaler tip: autoclaved under high temperature and high pressure	Different

Item	Proposed Device	Predicate Device (K163414)	Comparison
	the tooth cleaning tip with boiling water for five minutes, then wipe it dry and store it for next use		
Display Modes	Corresponding signal of external display driver circuit lights up corresponding LED.	Corresponding signal of external display driver circuit lights up corresponding LED.	Identical
Measurement Items	remove adherent plaque from the teeth and potential stains in the gingival groove, the back of the tooth and the tooth and associated gingival line.	Remove calculus or plaque on surface of teeth in oral cavity, cleaning and irrigation of root canals.	Similar
Power Supply	Input Voltag: 3.7VDC 50HZ Output Power: 2.8W	Input Voltage: 30VDC 50HZ Output Power: 3-20W	Different
Operating conditions	Temperature: 0-35°C Relative Humidity: <80%R.H Pressure: 70-106kpa	Temperature: 5°C-40°C Relative Humidity: 30%--80% Pressure: 50kpa-106kpa	Different
Storage conditions	Temperature: 0°C - +40°C Relative Humidity: <80%R.H. Pressure: 70-106kpa	Temperature: -10°C -+50°C Relativehumidity: ≤ 80% Pressure: 50kpa-106kpa	Different
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.	Different

Item	Proposed Device	Predicate Device (K163414)	Comparison
Electrical Safety	IEC 60601-1	IEC 60601-1	Identical
EMC	IEC 60601-1-2	IEC 60601-1-2	Identical
Performnce	IEC 60601-1-11	IEC 61205	Different
Biocompatibility	ISO 10993-5, ISO 10993-10	ISO 10993-5, ISO 10993-10	Identical
Software Level of Concern	Moderate	Moderate	Identical

Discussion

Similarities:

Measurement Items is similar.

Proposed Device: remove adherent plaque and food debris from the teeth to reduce tooth decay, potential stains in the gingival groove, the back of the tooth and the tooth and associated gingival line.

Predicate Device: Remove calculus or plaque on surface of teeth in oral cavity, cleaning and irrigation of root canals.

Difference:

Design:Operation Controls, Power Supply, Operating conditions and Storage conditions is slight different. However, Proposed Device has passed the Electrical Safety and EMC tests.

Performance: the requirement of performance standards is slight different. However, Proposed Device has passed the performance test.

- The difference does not raise additional questions for safety and effectiveness. Performance testing including biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives.

In conclusion, there is no substantial difference between our products and similar products currently marketed in the United States.

VII Performance data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the Ultrasonic Scaler was evaluated in accordance with ISO 10993-1:2018 for the body contact category of “Surface Device - Mucosal Membrane” with a contact duration of “Limited (< 24 hours)”. The following tests were performed, as recommended:

Cytotoxicity	ISO 10993-5: 2009

Skin sensitization	ISO 10993-10: 2021
Intracutaneous reactivity	ISO 10993-23: 2021

Non-Clinical Testing:

A battery of tests was performed to verify that the proposed device met all design specification. The test result demonstrated that the proposed device complies with the following standards:

Electrical safety and electromagnetic compatibility

IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2015 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-1-11:2015+AMD1:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 62471:2006 Photobiological safety of lamps and lamp systems

IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

VIII Conclusion

Conclusions drawn from non-clinical trials indicate that the subject device is as safe and effective as the legally marketed predicted K163414 ultrasonic scale and performs as well or better than the K163414 ultrasonic scaler.