September 8, 2022

ChangZhou BoMedent Medical Technology Co.,Ltd
Yang Chunyuan
Sales Manager
No.9 Changyang Road,West Taihu Science & Technology Industrial Park
Changzhou, Jiangsu 213100
China

Re: K213947
Trade/Device Name: Ultrasonic Endo Activation Device (Model:Actor I pro)
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: August 11, 2022
Received: August 12, 2022

Dear Yang Chunyuan:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For Michael E. Adjodha, M.ChE.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213947

Device Name
Ultrasonic Endo Activation Device (Model:Actor I pro)

Indications for Use *(Describe)*
The Ultrasonic Endo Activation Device (Model:Actor I pro) is an ultrasonic-handpiece which is intended use for root-canal cleaning and preparation.
The Ultrasonic Endo Activation Device (Model:Actor I pro) is intended for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.

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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510(K) Summary
K213947

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: September 6, 2022

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	ChangZhou BoMedent Medical Technology Co.,Ltd
Address:	No.9 Changyang Road,West Taihu Science & Technology Industrial Park, Changzhou, Jiangsu China.
Contact person:	Yang Chunyuan
Title:	sales manager
E-mail:	yang.chunyuan@bome-dent.com
Tel:	+86-15161150269

2. Device Identification

Trade/Device Name:	Ultrasonic Endo Activation Device
Models:	Actor I pro
Common name:	Scaler, Ultrasonic
Regulation Number:	21 CFR 872.4850
Regulation Name:	Ultrasonic scaler
Regulation Class:	Class II
Panel:	Dental
Product Code:	ELC

3. Predicate Device

510(K) number:	K202906
Device Name:	EndoPilot^2
Manufacturer:	Schlumbohm GmbH & Co. KG
Common name	Dental hand instrument
Regulation Number:	21 CFR 872.4850
Regulation Name:	Ultrasonic Scaler
Regulation Class:	Class II
Panel:	Dental
Product Code:	ELC Ultrasonic scaler EKX direct drive, AC-powered handpiece EKR endodontic plugger, root canal LQY root apex locator (unclassified)

4. Device Description

The subject device Ultrasonic Endo Activation Device (Model: Actor I pro) is an auxiliary device for dentists to perform root canal treatment. It is mainly used to clean the root canal with the help of ultrasonic cavitation, so as to assist dentists to complete root canal treatment.

The subject device Ultrasonic Endo Activation Device (Model: Actor I pro) configuration consist of the following components:

① ultrasonic handpiece ② ultrasonic working tip ③ Wrench ④ silicone case ⑤ charging base ⑥ Power Adapter⑦ wireless foot switch (Optional)

5. Indication for use

The Ultrasonic Endo Activation Device (Model:Actor I pro) is an ultrasonic-handpiece which is intended use for root-canal cleaning and preparation.

The Ultrasonic Endo Activation Device (Model:Actor I pro) is intended for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.

6. Summary of the device compared to the predicate device

Compared to the predicate device, the subject device has the same intended use, similar product design, same performance as the predicate device, summarized comparison information is listed in the following table:

SE Comparisons	**Subject Devices**	**Predicate Device** K202906	**Similarities/Differences**
Indication for Use	The Ultrasonic Endo Activation Device (Model:Actor I pro) is an ultrasonic-handpiece which is intended use for root-canal cleaning and preparation. The Ultrasonic Endo Activation Device (Model:Actor I pro) is intended for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.	The EndoPilot2 systems are dental devices which combine in a single control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for root-canal cleaning and preparation. The EndoPilot2 is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.	Similar Predicate device includes a single control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for root-canal cleaning and preparation. But Proposed device only include ultrasonic-handpiece which is intended use for root-canal cleaning and preparation. Function of proposed

			device is one of the functions of predicate device, there is no risk arise in aspect of indication for use.
Intermittent operation	3min	1 min/3 min (endodontic treatment)	Similar Subject device only has one mode, it can work for 3 minutes continuously. No new risk raised.
Vibration frequency	30±3kHz(27-33 kHz)	27 to 33 kHz	Same
Activation	By footswitch (optional), ON/OFF button	By footswitch, ON/OFF button	same
Patient contacting components	Ultrasonic working tip	Ultrasonic working tip	same
Power supply	Rechargeable Li-ion battery Capacity 1600mAh,3.7V	/	Different The subject device powered by a rechargeable Li-ion battery. The safety test results show no new safety risk raised.
Charger	Input: AC100-240V, 50/60Hz 0.2A Output: DC5V/1A	AC: 100-240 V, 50/60 Hz DC: 12 V, 1.5 A	Similar testing shows no new question raised
Bluetooth	BLE 5.0	4.1 Bluetooth	Different Meet EMC standard and FCC
Sterilization	Working Tip, Wrench and Silicone Case are user sterilized by steam sterilization.	handpiece and the tool are user sterilized by steam sterilization	Same
Electrical Safety	IEC 60601-1:2012 IEC 80601-2-60:2019	IEC 60601-1:2012 IEC 80601-2-60:2019	same
EMC	IEC 60601-1-2:2014	IEC 60601-1-2:2014	same
Biocompatibility	ISO 10993-5:2009 ISO 10993-10:2010 ISO 10993-11:2017	ISO 10993-5:2009 ISO 10993-10:2010	We conducted the acute systemic toxicity testing and pyrogen testing, test results show no biocompatibility risk.

All the differences don't affect substantial equivalence which is concluded after all the required testing.

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The proposed device Ultrasonic Endo Activation Device (Model: Actor I pro) complies with:

Safety and performance:

1. IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
2. IEC 80601-2-60:2012 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

Usability

3. IEC 60601-1-6:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Electromagnetic Compatibility:

4. IEC 60601-1-2:2014 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests

Biocompatibility:

5. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
6. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
7. ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Software Verification and Validation:

FDA software validation guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002".

Software documentation for moderate level of concern per the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Cleaning, intermediate level Disinfection, and Sterilization validation of the components of the subject

device per the FDA Guidance Document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, AAMI TIR 30, AAMI TIR 12, ISO 17665-1, and ISO17665-2.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is substantially equivalent to the legally marketed predicated device.