March 23, 2023

Foshan COXO Medical Instrument Co.,Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui. No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
CHINA

Re: K222096
Trade/Device Name: Endo Ultrasonic Activator
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: February 24, 2023
Received: February 24, 2023

Dear Ray Wang:

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,

Michael E. Adjodha -S

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)*
K222096

Device Name
Endo Ultrasonic Activator

Indications for Use *(Describe)*
For root canal cleaning.
The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

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.

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The assigned 510(k) Number: K222096

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation:2023/02/24

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name:Endo Ultrasonic Activator
Common Name: Scaler,Ultrasonic

Regulatory Information
Classification Name: Scaler,Ultrasonic
Classification: 2
Product Code: ELC
Regulation Number: 872.4850
Review Panel: Dental

Indication For Use Statement:
For root canal cleaning.
The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

Device description:
The Endo Ultrasonic Activator is mainly used for root canal cleaning.It mainly contain handpiece, sleeve, wrench, adapter and tip. The ultrasonic frequency generated by the CPU is driven by the drive circuit to drive the piezoelectric ceramic transducer, using the reverse piezoelectric effect to produce the ultrasonic vibration, motivating the working tip to produce the resonance, and using the cavitation and sound flow effect generated by the ultrasonic vibration to wash the root canal swing.

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K053555
Product Name: Ultrasonic Scaler(Model: UDS-L)
Manufacturer: Guilin Woodpecker Medical Instrument Company, Limited

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI/AAMI ES60601-1:2005 + A1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance.
- EC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the

basic safety and essential performance of dental equipment

- ISO 18397:2016 Dentistry-Powered scaler
- IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- 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.
- ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K053555 (Model:UDS-L)	Reference Device K213947	Remark
Device Name	Endo Ultrasonic Activator	Ultrasonic Scaler	Ultrasonic Endo Activation Device	/
Classification Regulation	872.4850	872.4850	872.4850	SAME
Classification Panel	Dental	Dental	Dental	SAME
Product Code	ELC	ELC	ELC	SAME
Common Name	Scaler,Ultrasonic	Scaler,Ultrasonic	Scaler,Ultrasonic	SAME
Indication for use	For root canal cleaning. The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.	1. Removing supra and sub gingival calculus deposits and stains from the teeth 2. Periodontal pocket lavage with simultaneous ultrasonic tip movement 3. Preparing,cleaning and irrigating root	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	SAME

		canals 4. Retrograde preparation of root canals	trained dental professionals in professional health care facilities on patients that needroot-canal-treatment.	
Input	Adapter AC100-240V 50/60Hz	Main Unit 24V 50Hz 1.3A	AC100-240V, 50/60Hz	Analysis(1)
Input Power	10VA	38VA	Not Available	Analysis(2)
Power supply	Battery 3.7V 1200mAh(Li-ion Battery)	Power source 220V 50HZ	Rechargeable Li-ion Battery Capacity 1600mAh,3.7V	Analysis(3)
Operating frequency	30kHZ±10%	28kHZ±3kHZ	30±3kHz(27-33 kHz)	Analysis(4)
Primary tip vibration excursion	<100μm	1μm-100μm	Not Available	SAME
Operation mode	Non-continuous	Continuous	Continuous	Analysis(5)
Classified of protection against Electric Shock	Class II	Class II	Not Available	SAME
Protection against Electric Shock	Type B applied part	Type BF applied part	Not Available	Analysis(6)
Degree of Protection	IPX0	General equipment IPX0	Not Available	SAME
Operating temperature	+5℃ - +40℃	+5℃ - +40℃	Not Available	SAME
Operating humidity	20% - 80%	30%-75%	Not Available	Similar
Atmospheric pressure	86kPa -106kPa	70kPa -106kPa	Not Available	Similar
Storage temperature	-10℃ - +55℃	-20℃ - +55℃	Not Available	Similar
Storage humidity	≤93%	10%-93%	Not Available	Similar
Atmospheric pressure	50kPa -106kPa	70kPa -106kPa	Not Available	Similar
Cordless	Yes	No	Yes	Analysis(7)
Device type	Handpiece	Unit	Handpiece	Analysis(7)
Biocompatibility	ISO10993-5 ISO10993-10	Not Available	ISO 10993-5:2009 ISO 10993-10:2010	Analysis(8)

			ISO 10993-11:2017	
Sterilization	ISO 17665-1	Not Available	Not Available	Analysis(8)
Electrical Safety	IEC 60601-1 IEC 80601-2-60	Not Available	IEC 60601-1:2012 IEC 80601-2-60:2019	Analysis(8)
EMC	IEC60601-1-2	Not Available	IEC 60601-1-2:2014	Analysis(8)
Dental	ISO 18397	Not Available	Not Available	Analysis(8)

Analysis：

Analysis(1):

There is difference on the input, the input of proposed device is adapter, the input of predicate device is main unit, however, both of them could meet the electricity safety standard IEC 60601-1, the difference does not affect the substantial equivalence in effectiveness and safety.

Analysis(2):

There is difference on the input power, however, both of them could meet the electricity safety standard IEC 60601-1, the difference does not affect the substantial equivalence in effectiveness and safety.

Analysis(3):

The proposed device is powered by rechargeable 3.7V Li-ion battery, and the predicate device is powered by AC power source, there is difference on the power supply mode. In principle, no matter what kind of power supply mode, piezoelectric ceramic transducer is driven electrically to drive the working tip to vibrate, and the intended use of root canal cleaning is achieved by using acoustic flow effect, hole effect and thermal effect generated by ultrasonic. In terms of type, the subject device drives the transducer through battery power, while the transucer of the predicate device is powered by AC power source, and it may need to drive the transducer through a transformer. But the vibration generated by the current driven transducer and the ultrasonic are essentially the same. So the difference would not affect its effectiveness.The proposed device comply with electrical safety standard IEC 60601-1, and its Li-ion battery comply with the battery safety standard IEC 62133-2, so the power supply mode difference would not affect its safety.

In addition, powered by battery is a very common power supply mode. For example, the Reference Device K213947 we determined uses the battery to supply power.

This reference device K213947 is consistent on the indication for use, technological characteristics and other relevant information with the subject device.

By comparing with the reference device, we can find that the intended use of the subject device is consistent with the reference device. Both the subject device and the reference device are based on the principle of ultrasonic vibration for root canal cleaning. And the reference device, like the subject device, is also a cordless, battery-powered device.

And the reference device is also use the 3.7V Li-ion battery which is same with the subject device. Thus, powered by a battery is a very mature technology.

Analysis(4):

The proposed devices and the predicate device are different operating frequency. Operation frequency of

the subject device is only slightly different with the predicate device.
And we have also identified the reference device K213947 which is consistent with the operation frequency of the subject device.
We believe that the difference of the operating frequency of the subject device and predicate will not affect the substantial equivalence of safety and effectiveness.

Analysis(5):
The proposed devices and the predicate device are difference operation mode.The operating mode of the proposed devices are comply with the 60601-1, so this could not effect the effectiveness and safety.

Analysis(6):
The proposed devices and the predicate device are difference Protection against Electric Shock.The Protection against Electric Shock of the proposed devices are comply with the 60601-1, so this could not effect the effectiveness and safety.

Analysis(7):
There are some design differences between the subject device and the predicate device, for example, cordless and hanpiece. However, we believe that the design differences will not affect the safety and efficacy of the subject device.

First, in principle, the unit of the predicate device is connected to a power supply to power the CPU, and the software is built into the unit.
The unit and the handpiece through the cable connection. This cable is used to power the handpiece and transmit signals to the handpiece, and thus realize the functions of the product.
The subject device, the software is built into the handpiece. After battery power, it drives the transducer to control the CPU and set the function.
No matter how the power supply and signal transmission, the power supply ultimately drives the CPU to work and realize various functional settings of the product. The electrical structure is consistent in essence, only the appearance changes and the connection mode is not consistent, leading to the different selection of CPU, which will not affect the product to achieve the final intended use. So from a principle point of view we are the same as the predicate device, just the form of power supply and the signal transmission have changed.
Because of the connection mode changes, we introduced software validation to prove that functionality of the subject device can be fully implemented. And we introduced ISO 18397 testing to prove that our performance implementation meets the requirements.

In addition, the reference device K213947 we determined is also a cordless handpiece device, and both the subject device and the reference device are based on the principle of ultrasonic vibration for root canal cleaning, which shows that this design form is a very mature technology and will not affect the safety and effectiveness of the subject device.

Analysis(8):
We did not obtain relevant test information for the predicate device, We discuss here to make it clear that these minor differences are not concerns for the equivalency of the proposed device and predicate device.

And will not affect the performance of safety and effectiveness of the proposed device.

a.We performed applicable tests to support biocompatibility, including Cytotoxicity, Sensitization and Irritation.
ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. Biocompatibility testing of in vitro cytotoxicity was performed to verify the equivalent safety of the materials that are in direct contact with mucosal membrane and teeth in the mouth, and skin including tip and sleeve.
ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization Biocompatibility testing for Irritation and Skin Sensitization was performed to verify the equivalent safety of the materials that are in direct contact with mucosal membrane and teeth in the mouth, and skin including tip and sleeve.
b.Sterilization validation testing is performed in accordance with ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices. But Reprocessing methods also meet the FDA Guidance Document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."
c.Electrical safety testing per IEC 60601-1 and IEC 80601-2-60 required testing.
d.Electromagnetic Compatibility testing per IEC 60601-1-2 required testing.
e.The functions of Endo Ultrasonic Activator were verified according to ISO 18397: 2016 Dentistry - Powered scaler. Performance test performed on proposed device aims to support the substantial equivalence of the proposed device to the predicate device. Test’s setup and execution was in accordance with applicable standards. Results of the testing demonstrate the comparable performance (eg:Operating frequency) between proposed device and predicate device.

9. Substantially Equivalent (SE) Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, Ultrasonic Scaler cleared under K053555.