June 30, 2020

ChangZhou BoMedent Medical Technology Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
R912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, 102401
CHINA

Re: K191276
Trade/Device Name: Dental Electrical Motor iRoot Pro
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EKX, LQY
Dated: May 29, 2020
Received: June 1, 2020

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,

For Srinivas "Nandu" Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191276

Device Name

Dental Electrical Motor iRoot Pro

Indications for Use *(Describe)*

The Dental Electrical Motor iRoot Pro is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.

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

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.

The assigned 510(k) Number: K191276

1. Date of Preparation: June 30, 2020

2. Sponsor Identification

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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Dental Electrical Motor iRoot Pro
Common Name: Dental Handpiece and Accessories
Model(s): iRoot Pro

Regulatory Information
Classification Name: Dental Handpiece and Accessories
Classification: 1
Product Code: EKX/LQY
Regulation Number: 21 CFR 872.4200
Review Panel: Dental;

Indications for Use Statement:
The Dental Electrical Motor iRoot Pro is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.

Device Description
The Dental Electrical Motor iRoot Pro is a low-speed rotating oral equipment mainly used for root canal preparation and root canal measurement. The product is a portable device powered by built-in lithium batteries and charged by USB interface. LCD displays parameters such as speed, torque, working mode, apex position, etc. Users can also set and modify by keys, and provide design of factory initialization and calibration. The product also provides a complete rotation mode and root canal measurement mode, which can be stored in memory, and provides a key functional mode for users to use quickly.
The Dental Electrical Motor iRoot Pro is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.
The Dental Electrical Motor iRoot Pro is intended to be sterilized prior to use.

There are four working modes as:

Mode: Only endo motor function enabled;

Mode: Endo motor and apex locator work independently， when the file reaching the apical, the apex locator only plays the role of warning and display， will not interfere with the rotation of endo motor, the motor will not stop and reverse when the file reach the apical.

Mode: In this mode, the motor will automatically rotate, stop, reverse depends on the length of the root canal measured by the apex locator.

The chuck of proposed device needs to be used with the file in accordance with Type 1 in ISO 1797-1, the diameter of chuck interface is Φ1.5.

The lubricant to be used with the contra angle is "DO-ALL Dental Handpiece Lubricant" manufactured by ProDrive Systems Inc., which has been cleared as K073353.

5. Identification of Predicate Device(s)

Primary Predicate Device:
510(k) Number: K170275
Product Name: Tri Auto ZX2
Manufacturer: J. Morita USA, Inc.

Reference Device:
510(k) Number: K153285
Product Name: EMS-200
Manufacturer: Meta Systems Co., Ltd.

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:

a. IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
b. IEC 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
c. ISO 14457:2017 Dentistry - Handpieces and motors
d. ISO 80601-2-60:2012 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
e. ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
f. ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity
g. 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 ISO 17665-2. In addition, disposable barrier sleeve anti-contamination and ingress verification testing

was conducted.

h. 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.”

i. Apex Locator Performance Testing to verify the apex locator measuring accuracy performance

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(s)	Predicate Device(s)	Reference Device	Remark
Device name	Dental Electrical Motor iRoot Pro	Tri Auto ZX2	EMS-200	/
Classification Name	endodontic treatment motorized handpiece/ root canal apex locator	endodontic treatment motorized handpiece/ root canal apex locator	endodontic treatment motorized handpiece	SAME
Product Code	EKX/LQY	EKX/LQY	EKX	SAME
Regulation Number	872.4200	872.4200	872.4200	SAME
Comparison Statement	**The proposed device has same classification information as the predicate device.**			
Intended Use	The Dental Electrical Motor iRoot Pro is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length.	The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low speed motorized handpiece and device for measuring canal length.	The EMS-200 is a dental device which combines in a single LCD unit an endo motor which ablates the tooth to expand the root canal, a dental obturator to fill and pressurize various shaped packing elements and an electronic apex locator which assists the operator the location of the front tip in the root canal, for use by trained dental professionals.	SAME
Usage	Prescription Use	Prescription Use	Prescription Use	SAME
Comparison Statement	**The proposed device has same intended use as the predicate device.**			
Technical Specifications				
Energy used and/or	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	DC 12 V	SAME

delivered				
Dimension	280 x 25 x 26mm(central unit include contra angle) 123 x 61 x81mm (battery charger)	30 mm x 30mm x 200 mm Charger: 85 mm x 85mm x 75 mm	148.1 mm x 187.6 mm x 45 mm	SIMILAR
Speed	100-1000 rpm	100-1000 rpm	250-800 rpm	SAME
Gear Ration	16:1	Not Available	16:1	SAME
Torque	0.1-4.0 N.cm	4 N.cm	0.6-5.0 N.cm	SAME
Accuracy of the root apex locator function	-1.5mm to+0.5mm for Apex position	-1.5mm to+0.5mm for Apex position	-0.5mm to +0.5mm	SAME
Spray Nozzle	Spray nozzle	Spray nozzle	Not Available	SAME
Sterility	Lip clip, and contra angle are autoclavable. The central unit and lip hook cable are covered with an FDA cleared barrier sleeve and intermediate level disinfected.	File holder, contrary electrode, and contra Angle are autoclavable.	Not Available	SAME
Feature	Canal measurement, alarm, canal length indicator	Canal measurement, alarm, canal length indicator	Canal measurement	SAME

Operation Mode	R Mode: Only apex locator measurement function enabled. M Mode: Only endo motor function enabled; MR Mode: Endo motor and apex locator work independently，when the file reaching the apical, the apex locator only plays the role of warning and display，will not interfere with the	EMR mode: This mode is for canal measurement, the motor does not run in this mode. CW mode: The motor rotates for forward 360, torque reverse and other functions can be used. OGP mode: The OGP (Optimum Glide Path) function is used for canal negotiation and making the glide path. OTR mode: The OTR (Optimum Torque Reverse) function is used for canal shaping. CCW Mode: The motor rotates	Not Available	SAME

	rotation of endo motor, the motor will not stop and reverse when the file reach the apical.  Mode: In this mode, the motor will automatically rotate, stop, reverse depends on the length of the root canal measured by the apex locator.	counterclockwise direction only.		
Principle of operation	Electrical motor drives the rotating of file equipped on the rotating to accomplish it's indication for use. And the software control the parameter and method of rotating.	Electrical motor drives the rotating of file equipped on the rotating to accomplish it's indication for use. And the software control the parameter and method of rotating.	The Motor rotates the motor-operated file(Ni-Ti file) by pressing the operation button on the micro-motor handpiece which expands or shapes the root canal by using the rotating power of the electric file (Ni-Ti file). Micro signals consisting of dual frequencies coming from the main unit return to where they are sent after travelling along the electric circuit that is composed of 'main unit – probe cord – file holder–file – patient – lip holder –probe cord'. Pack handpiece provides instantaneous heating and cooling of the heat plugger with precisely controlled temperature and timing. FILL handpiece is designed to inject	SAME

			warmed Gutta percha that is specially formulated into the root canal directly.	
Patient Contacting Materials	Silica rubber and 304 stainless steel	Not Available	Silica rubber, stainless steel	Difference
Comparison Statement:	**The proposed device has the same main specifications with the predicate device but only minor difference in dimension, which caused by different appearance design and do not effect the performance.** **The Patient contacting materials of predicate device could not be identified, so it considered as difference. For this difference, the biocompatibility tests as ISO 10993 series standards have been conducted, the test results shown that the patient contacting materials of proposed could not causes safety concerns.**			
Applied Standards:				
Biocompatibility	ISO10993-5&ISO10993-10&ISO 10993-11	ISO10993-5&ISO10993-10&ISO 10993-11	ISO10993-10	SAME
Electrical Safety	IEC60601-1	IEC60601-1	IEC60601-1	SAME
EMC	IEC60601-1-2	IEC60601-1-2	IEC60601-1-2	SAME
Performance	IEC 80601-2-60 ISO 14457	ISO 14457	ISO 14457	SAME
Comparison Statement	**The proposed probe has same applied Standards with the predicate device.**			

9. Substantially Equivalent (SE) Conclusion

The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.