May 10, 2021

Guilin Woodpecker Medical Instrument Co., Ltd.
% Giselle Zhang
Regulatory Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K203320
Trade/Device Name: Endo Motor
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: April 13, 2021
Received: May 10, 2021

Dear Giselle Zhang:

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 Adjodha
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K203320

Device Name

Endo Motor

Indications for Use *(Describe)*

Endo Motor, Ai-Motor and Endo Radar Plus are cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used for preparation and enlargement of root canals, or measuring the canal length. And it can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary K203320

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

5.1 Submitter Information

Company:	Alex Wang Registration & Certification GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD Information Industrial Park, Guilin National High-Tech Zone Guilin, Guangxi 541004 P.R. China Telephone: 0086-773-2350532 Fax: 0086-773-5822450 zmnbg03@glwoodpecker.com
Contact:	Giselle Zhang Regulatory Consultant Emergo Global Consulting, LLC 2500 Bee Cave Road, Building 1, Suite 300 Austin, Texas 78746 USA Telephone: (512) 327-9997 Fax: (512) 327-9998 LST.AUS.ProjectManagement@ul.com
Date Summary Prepared:	March 29, 2021

5.2 Device Name and Regulatory Information

Trade Name:	Endo Motor
Common Name:	Dental handpiece and accessories
Classification Name:	Dental
Review Panel:	Dental (DE)
Regulation:	872.4200
Class:	Class I
Product Code:	EKX

5.3 Equivalence Claimed to Predicate Device

The Endo Motor is equivalent to the Tri Auto ZX2 (K170275), manufactured by J. MORITA USA, INC.. XSmart iQ (K161213) is provided as a reference device.

5.4 Device Description

The Endo Motor Series includes a cordless hand-piece with charging adapter. The device has a chuck for holding rotary instruments such as dental files, and is mainly used in Endodontic surgeries. The device can enlarge the root canal by filing the dentin and measuring the root canal length, and may also be used for cutting and grinding for the preparation of root canal surgery. The rotary speed and the torque range can also be adjusted.

5.5 Intended Use Statement

Endo Motor, Ai-Motor and Endo Radar Plus are cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used for preparation and enlargement of root canals, or measuring the canal length. And it can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

5.6 Non-Clinical Testing

To demonstrate substantial equivalence in safety and effectiveness of Endo Motor Series to the predicate device, Woodpecker completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The Endo Motor Series passed the testing in accordance with internal requirements, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device :

- Cytotoxicity testing per ISO 10993-5 – Passed
- Sensitization testing per ISO 10993-10 – Passed
- Electrical safety testing per IEC 60601-1 – Passed
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2 – Passed
- Software verification and validation per IEC 62304/FDA Guidance – Met Requirements
- Usability per IEC 62366-1 – Met specifications
- Shipping Containers and Systems Performance, per ASTM D4169 – Demonstrates package integrity maintained
- Dental Performance Requirements, per IEC 80601-2-60 – Passed Processing of Medical Device, per ISO 17664 – Passed
- Development, Validation and Routine Control of Sterilization Process, per ISO 17665-1 – Passed Moist Heat Sterilization, per ISO TS 17665-2 – Passed
- Dentistry - Handpieces and Motors, per ISO 14457 – Passed
- Performance Comparison Testing of Root Canal Measurement - Passed

5.7 Substantial Equivalence Discussion

Both Tri Auto ZX2 and Endo Motor Series are battery-driven handpieces with a motor, equipped with a chuck for holding rotary instruments such as a dental file. Both devices can be used for cutting and grinding teeth by transferring rotary movement to a rotary instrument attached to the head. Cutting and grinding of teeth can be done depending on switching/reversing the rotation direction. Rotation speed is accelerated or deceleratedaccording to the user's preference, rotation control is based on torque detection, or pre-set time. These controls enable the cutting, grinding, enlargement, and preparation of root canals. Both devices can be used as an apex locator, and the measured value can be used for rotation control. Also both devices are intended to be sterilized prior to use.

The Tri Auto ZX2 can be used for the removal of extraneous materials such as gutta-percha points, and for professional mechanical tooth cleaning.

The XSmart iQ is used as a reference device. As for the XSmart iQ, the Endo Motor series includes cordless motor hand-pieces, and both devices have a console. The Endo Radar Plus has integrated the display on the base but XSmart iQ is based on an Apple iPad Mini®. The motor parameters can be transferred, stored and displayed via the base on the Endo Radar Plus, but XSmart iQ uses iPad Mini® application (Endo iQ app).

Table 5.1: Substantial Equivalence Discussion			
Attribute	Endo Motor, Ai- Motor	Endo Motor, Endo Radar Plus	Tri-Auto ZX2 K170275 (Primary)
Manufacturer	GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD	GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD	J. MORITA USA, INC.
Intended Use	Canal Enlargement Root Canal Length Measurement	Canal Enlargement Root Canal Length Measurement	Canal Enlargement Root Canal Length Measurement
Indication for Use	Endo Motor, Ai- Motor is a cordless endo motor with root canal measurement capability. It can be used as a endo motor for preparation and enlargement of root canals, or device for measuring canal length. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal.	Endo Motor, Ai- Motor and Endo Radar Plus are cordless endodontic motor with root canal measurement capability. It can be used as a endo motor for preparation and enlargement of root canals, or device for measuring canal length. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal.	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.
Target Population	Patients in need of root canal surgery	Patients in need of root canal surgery	Patients in need of root canal surgery
Anatomical Sites	Root canal Softened dentin	Root canal Softened dentin	Root canal Softened dentin
Where Used	Dental Clinic University Hospital The other clinical settings	Dental Clinic University Hospital The other clinical settings	Dental Clinic University Hospital The other clinical settings
Dimension	Motor Handpiece: 28 mm × 33.7 mm × 199.2 mm	Motor Handpiece: 27.8 mm × 29 mm × 212 mm	Motor Handpiece: 30 mm x 30 mm x 200 mm
Weight	150g	151g	140g
User Interface	Four push buttons: ON/OFF Setting button Adjusting button “+” Adjusting button “-”	Push Button of Handpiece: ON/OFF Touch Button of Base: “Power” button: Control the power on or off. “Auto Rev” button “REV” button “En-Ap” button “SET” button “SYSTEM” adjusting button “FILE” button “TORQUE” button “SPEED” button “ANGLE” button	Four push buttons: ON/OFF Setting button Adjusting button “+” Adjusting button “-”
Materials of Motor Handpiece	PC/PBT blend (PC-Polycarbonate, PBT-polybutylene terephthalate)	PC/PBT blend (PC-Polycarbonate, PBT-polybutylene terephthalate)	PC/PBT blend (PC-Polycarbonate, PBT-polybutylene terephthalate)
Power Supply	Rechargeable	Lithium-ion battery (DC	Lithium ion battery: 3.7V

	lithium battery (3.7V)	3.7 V)	
Charger Power Supply	AC100V-240V	AC100V-240V	AC100V-240V
Frequency of Supply Voltage	50Hz ~ 60Hz	50Hz ~ 60Hz	50Hz ~ 60Hz
Components	Measuring wire File clip Lip hook Touch probe Silicon Cover Tester Spray Nozzle	Measuring wire File clip Lip hook Touch probe Silicon Cover Tester Spray Nozzle	Tester Spray Nozzle
Safety Mechanism	Automatically stops or reversely rotates as soon as the file reaches the apical stop, so as to prevent perforation.	Automatically stops or reversely rotates as soon as thefile reaches the apical stop, so as to prevent perforation.	Auto Torque Reverse: The OTR (Optimum Torque Reverse) function enables the file to reverse its rotational direction upon reaching a certain torque. After rotating in reverse by 90 degrees, the file returns to the cutting direction.
Battery Indicator	When the blue indicator on the charging base flashes, it is charging. When the motor handpiece is fully charged, the blue indicator on the charging base would be always on.	Motor hand-piece battery level is displayed on base. The battery sign on the base screen is full to indicate the fully charged state. The battery sign on the base screen is only 2/3 to indicatethe remaining battery power is about 70%. The battery sign on the base screen is only 1/3 to indicatethe remaining battery power is about 30%. The battery sign on the base screen is blank to indicate the battery is very low, please charge in time. When charging, the screen display panel green power icon will scroll display, when the battery power sign no longer scroll display, indicating that the battery was fully charged.	The orange light indicates charging. The green light indicates full charge.
Torque Range	0.4 Ncm ~ 5 Ncm	0.4 Ncm ~ 5 Ncm	0.4 Ncm ~ 4 Ncm
Rotate Speed	100 rpm~1200 rpm (File in rotary mode)	100 rpm~1200 rpm (File in rotary mode)	100 rpm~1000 rpm (File in rotary mode)
Adjustability of Speed and Torque	0.5 Torque setting(Ncm) 50 speed steps	0.5 Torque setting (Ncm) 50 speed steps	0.2 Torque setting(Ncm) 75 speed steps
Micro Motor	Brushless	Brushless	Brush
USB Ports	Yes	Yes	Yes
Contra Angle Attachments	6:1 Contra Angle (Model: CA161)	6:1 Contra Angle (Model: CA161)	Morita Contra Angle Specific (Exclusive) to TriAuto ZX2
Primary Contra Angle Gear Ratio	6:1	6:1	6:1
Operation Mode	Continuous operation	Continuous operation	Continuous operation

Biocompatibility	Conforms to 10993 Standards	Conforms to 10993 Standards	Conforms to 10993 Standards
Sterilization	End User (Moist Heat)	End User (Moist Heat)	End User (Moist Heat)
Electrical Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Conform to IEC 60601-1
Mechanical Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Conform to IEC 60601-1
Thermal Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Conform to IEC 60601-1
EMC Safety	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2

5.8 Conclusion

The Endo Motor Series has the same intended use and the same or similar technological characteristics and functionality as the predicate, and therefore is substantially equivalent to the predicate device. The differences are minor and supported by the reference device to demonstrate they do not raise new questions of safety and effectiveness as compared to the predicate device.