January 29, 2021

Changzhou Sifary Medical Technology Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue. Nanshan District
Shenzhen,, Guangdong 518067
CHINA

Re: K201993
Trade/Device Name: E-connect S Endo Motor with built-in Apex Locator
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EKX, LQY
Dated: January 15, 2021
Received: January 19, 2021

Dear Kevin 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, M.ChE.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K201993

Device Name

E-connect S Endo Motor with built-in Apex Locator

Indications for Use *(Describe)*

E-connect S is a cordless endodontic treatment motorized handpiece with root canal measuring 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.
This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

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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510(K) Summary

K201993

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: January 26, 2021

1. Submission sponsor

Name: Changzhou Sifary Medical Technology Co., Ltd.
Address: No. 99, Qingyang Road, Xuejia County, Xinbei District, Changzhou City, Jiangsu Province, 213000, P.R. China
Contact person: Amanda Zhu
Title: RA Specialist
E-mail: amanda@sifary.com
Tel: +86 0519-85962691

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
Address: Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P. R. China 518067
Contact person: Kevin Wang
E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	E-connect S Endo Motor with built-in Apex Locator
Model	E-connect S
Common Name	Endodontic treatment motorized handpiece/ root canal apex locator
Regulatory Class	Class I
Regulation	21CFR 872.4200
Classification Name	Dental handpiece and accessories
Primary Product code	EKX
Secondary Product Code	LQY
Submission type	Traditional 510(K)

4. Predicate Device

Manufacturer: J. Morita USA, Inc.
Device name: Tri Auto ZX2
510(K) Number: K170275

5. Reference Device

Manufacturer: ChangZhou BoMedent Medical Technology Co., Ltd.
Device name: Dental Electrical Motor iRoot Pro
510(K) Number: K191276

6. Device Description

The E-connect S is a battery-driven handpiece with a motor, equipped with a chuck for holding rotary instruments such as a dental file. The E-connect S can be used for enlargement and preparation of root canals and can also be used as an apex locator.

The motor drives the file to rotate at a certain speed and torque through the contra angle gearing. The rotating file will cut the root canal wall along the direction of the root canal. The speed and torque of the motor are controlled by the central processor and are configurable to accommodate different files. With built-in apex locator, this device monitors the file tip position in the root canal during root canal treatment.

The components of the E-connect S include a charge base, handpiece, contra angle, insulating sleeve, file clip, lip hook, measuring wire, adapter, and spray nozzle. The contra angle is compatible with files shafts conforming to ISO 1971-1, Type 1. The key panel on the handpiece is used to control/adjust the power, memory settings, operation modes (motor/apex,) and adjust the parameters. The body of the handpiece is to be covered with a FDA cleared barrier sleeve.

7. Intended use & Indication for use

E-connect S is a cordless endodontic treatment motorized handpiece with root canal measuring 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.
This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

8. Comparison to the Predicate Device

Features	**Subject Device** **E-connect S**	**Predicate Device** **K170275** **Tri Auto ZX2**	**Reference device** **K191276** **Dental Electrical Motor iRoot Pro**	**Comparison**
Applicant	Changzhou Sifary Medical Technology Co., Ltd.	J. Morita USA, Inc.	ChangZhou BoMedent Medical Technology Co., Ltd.	/
Classification Regulation	21CRF 872.4200	21CRF 872.4200	21CRF 872.4200	Same
Classification	Class I	Class I	Class I	Same

Features	**Subject Device** **E-connect S**	**Predicate Device** **K170275** **Tri Auto ZX2**	**Reference device** **K191276** **Dental Electrical Motor iRoot Pro**	**Comparison**
and Code	EKX, LQY	EKX, LQY	EKX, LQY	
Common name	Endodontic treatment motorized handpiece/ root canal apex locator	Endodontic treatment motorized handpiece/ root canal apex locator	Endodontic treatment motorized handpiece/ root canal apex locator	Same
Indications for use	E-connect S is a cordless endodontic treatment motorized handpiece with root canal measuring 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. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	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 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.	Same
Patient populations	Adult	Patient population is age 12 and older	Not known	Different (1)
Anatomical sites	Root canal, softened dentin	Root canal, softened dentin	Root canal, softened dentin	Same
Where used	Dental clinic, University hospital and the other clinical settings	Dental clinic, University hospital and the other clinical settings	Dental clinic, University hospital and the other clinical settings	Same
Energy used and/or delivered	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	Same
Exterior Design	21.5cm × 17.5cm × 9cm	30 mm × 30mm × 200 mm Charger: 85 mm × 85mm × 75 mm	280 × 25 × 26mm(central unit include contra angle) 123 x 61 x81mm	Different (2)

Features	Subject Device E-connect S	Predicate Device K170275 Tri Auto ZX2	Reference device K191276 Dental Electrical Motor iRoot Pro	Comparison
			(battery charger)	
Performance 1 - canal enlargement	120-1000 rpm 0.5N·cm –4N·cm	100-1,000rpm 4Ncm (min.)	100-1000 rpm 0.1-4.0 N·cm	Different (3)
Performance 2 - apex locator	Accuracy of the root apex locator function: -0.5mm to +0.5mm for Apex position.	Accuracy of the root apex locator function: -1.5mm to +0.5mm for Apex position.	Accuracy of the root apex locator function: -1.5mm to +0.5mm for Apex position.	Different (4)
Materials	Used materials conform to ISO10993.	Used materials conform to ISO10993.	Used materials conform to ISO10993.	Same
Spray nozzle	Spray nozzle	Spray nozzle	Spray nozzle	Same
Compatibility with environment and other devices	Conform to IEC60601-1-2	Conform to IEC60601-1-2	Conform to IEC60601-1-2	Same
Sterility	Contra Angle, Lip Hook, File clip, Insulating Sleeve autoclavable.	File holder, contrary electrode, and contra Angle are autoclavable.	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.	Different (5)
Electrical safety	Conform to IEC60601-1	Conform to IEC60601-1	Conform to IEC60601-1	Same
Mechanical safety	Conform to IEC60601-1	Conform to IEC60601-1	Conform to IEC60601-1	Same
Thermal safety	Conform to IEC60601-1	Conform to IEC60601-1	Conform to IEC60601-1	Same
Radiation safety	Conform to IEC60601-1-2	Conform to IEC60601-1-2	Conform to IEC60601-1-2	Same

Justifications for differences between proposed device and the predicate device are shown as below:

Different (1): Target population in the E-connect S is included in that of the predicate devices, thus, this difference has no influence on substantial equivalence.

Different (2): The exterior design of the E-connect S compared to the Tri Auto ZX2 has slightly changed

for design. However, the structures of both devices which include the contra angle that connects and rotates the files, the probe for measuring the root canal length, and the built-in root canal length measurement function are substantially equivalent. Moreover, the principle of controlling the rotation by measurement result, load value, setting etc. is also substantially equivalent.

Different (3): The rotation speed of E-connect S is within the speed of the predicate device, thus substantially equivalent.

Different (4): The principle of the root canal length measurement function of the E-connect S is the same as the predicate device.

Different (5): The sterility validation was performed according to ISO 17665-1. Thus, this difference does not raise different questions of substantial equivalence.

9. Performance Data

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

Biocompatibility testing

The biocompatibility evaluation for E-connect S was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity (ISO 10993-5: 2009)
- Sensitization (ISO 10993-10: 2010)
- Irritation (Oral mucosa) (ISO 10993-10: 2010)

The subject devices are considered surface contacting for a duration of not exceed 24 hours.

Non-clinical data

The E-connect S has been tested according to the following standards:

- IEC 60601-1-2005+CORR.1:2006+CORR.2:2007+A1:2012, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance
- 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
- IEC 80601-2-60: 2012 Medical Electrical Equipment - Part 2-60: Particular Requirements for Basic Safety and Essential Performance of Dental Equipment.
- ISO 14457: 2017 Dentistry – Handpieces and motors
- Moderate level of software documentation per the FDA Guidance for Software Contained in Medical Devices.
- Reprocessing validation (i.e., cleaning, disinfection, and sterilization) per the FDA Guidance Document for Reprocessing Medical Devices in Healthcare Setting.
- Comparative Root Canal Measurement Performance Test to evaluate the root canal length

measurement accuracy to the predicate device.

The test was selected to show substantial equivalence between the subject device and the predicate.

Clinical data

There were no clinical tests performed for the E-connect S device.

10. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.