April 26, 2023

Shenzhen Perfect Medical Instruments Co., Ltd.
% Jarvis Wu
Consultant
Shanghai Sungo Management Consulting Company Limited
14th floor, 1500# Century Ave.,
Shanghai, Shanghai 200122
CHINA

Re: K222548
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, LQY
Dated: January 30, 2023
Received: January 30, 2023

Dear Jarvis Wu:

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 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)*
K222548

Device Name
Endo Motor

Indications for Use *(Describe)*
The Endo Motor, model: ZR-Rap, 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

K222548

Document Date Prepared:2022/8/12

A. Applicant:

Name: Shenzhen Perfect Medical Instruments Co., Ltd.

Address: Room 102, Building A, Ruiji Factory, No. 3 Zaohekeng, Jixia Community, Nanwan Street, Longgang District,Shenzhen, P.R. China. 518100

Contact Person: Kristy Mo

Tel: +86- 13929326975

Mail: kristy@medtung.com

Submission Correspondent:

Primary contact: Mr. Jarvis Wu

Shanghai SUNGO Management Consulting Co., Ltd.

14th floor, 1500# Century Ave., Shanghai 200122, China

Tel: +86-21-58817802

Email: haiyu.wang@sungoglobal.com

Secondary contact: Mr. Raymond Luo

14th floor, 1500# Century Ave., Shanghai 200122, China

Tel: +86-21-68828050

Email: fda.sungo@gmail.com

B. Device:

Proprietary Name: Endo Motor

Common Name: Endodontic treatment motorized handpiece with built-in apex locator

Model(s): ZR-Rap

Regulatory Information

Classification Name: Dental handpiece and accessories

Classification: Class I

Primary Product code: EKX

Secondary Product Code: LQY

Regulation Number: 878. 4200

C. Predicate device:

Manufacturer: Changzhou Sifary Medical Technology Co., Ltd.

Device name: E-Connect S Endo Motor With Built-In Apex Locator

510(K) Number: K201993

(Note: Predicate device has NOT been subject to any Medical Device Recalls, including design-related recall.)

D. Indications use of the device:

The Endo Motor, model: ZR-Rap, 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.

E. Device Description:

The Endo Motor, model: ZR-Rap, is a battery-driven handpiece with a motor, equipped with a chuck for holding rotary instruments such as a dental file. The Endo Motor can be used for enlargement and preparation of root canals and can also be used as an apex locator.

F. Comparison with predicate device

Table 1 General Comparison

Device	**Proposed Device**	**Predicate device**	**Comparison**
Manufacturer	Shenzhen Perfect Medical Instruments Co., Ltd.	Changzhou Sifary Medical Technology Co., Ltd.	-
510K number	K222548	K201993	-
Device name	Endo Motor	E-connect S Endo Motor	-
Classification Regulation	21CRF 872.4200	21CRF 872.4200	Same

Classification	Class I	Class I	Same
Product Code	EKX, LQY	EKX, LQY	Same
Common name	Endodontic treatment motorized handpiece with built-in apex locator	Endodontic treatment motorized handpiece with built-in apex locator	Same
Indications for use	The Endo Motor, model: ZR-Rap, 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.	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.	Same
Patient populations	Adult	Adult	Same
Anatomical sites	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	Same
Energy used and/or delivered	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	Same
Exterior Design	28.2cm × 19.0cm × 6.2cm	21.5cm × 17.5cm × 9cm	Similar
Performance 1 – canal enlargement	150rpm-650rpm 0.6N.cm-4N.cm	120-1000 rpm 0.5N·cm –4N·cm	Different
Performance 2 - apex locator	Accuracy of the root apex locator function: -0.5mm	Accuracy of the root apex locator function: -0.5mm	Same

	to +0.5mm for Apex position.	to +0.5mm for Apex position.	
Materials Biocompatibility	Used materials conform to ISO10993.	Used materials conform to ISO10993.	Same
Spray Nozzle	Spray nozzle (Oil injector)	Spray nozzle	Same
Compatibility with environment and other devices	Conform to IEC60601-1-2	Conform to IEC60601-1-2	Same
Sterility	Contra Angle, Lip Hook, File clip, Protective silicon cove	Contra Angle, Lip Hook, File clip, Insulating Sleeve autoclavable.	Same
Electrical safety	Conform to IEC60601-1	Conform to IEC60601-1	Same
Mechanical safety	Conform to IEC60601-1	Conform to IEC60601-1	Same
Thermal safety	Conform to IEC60601-1	Conform to IEC60601-1	Same
Radiation safety	Conform to IEC60601-1-2	Conform to IEC60601-1-2	Same

Different Analysis:

The rotation speed of Endo Motor is within the speed range of the predicate device, and it has passed performance test, no affect on safety or efficacy.

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. The test results demonstrated that the proposed device complies with the following standards and FDA Guidance:

- 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
- 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: 2019 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

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the Endo Motor (Model: ZR-Rap) is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201993.