March 12, 2021

Foshan CICADA Dental Instrument Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai road, Science City, LuoGang District
Guangzhou, Guangdong
CHINA

Re: K192649
Trade/Device Name: Endo Motor Model: T-Fine-II
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: February 7, 2021
Received: February 10, 2021

Dear Jet Li:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192649

Device Name
Endo Motor Model: T-Fine-II

Indications for Use *(Describe)*

Endo Motor T-Fine-II is indicated for use in standard endodontic procedures using rotary endodontic files for mechanical and rotary preparation of the root 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.

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Chapter 6. 510(k) Summary

510(k) Summary - K192649

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 872.6070.

1. Submitter Information

Sponsor: Foshan CICADA Dental Instrument Co, Ltd .

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Application Correspondent: Jet Li

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Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Handpiece, Direct Drive, Ac-Powered
- Trade Name: Endo Motor Model: T-Fine-II
- Classification Name: Dental Handpiece and accessories

- Review Panel: Dental
- Product Code: EKX
- Regulation Number: 21 CFR 872.4200
- Regulation Class: 1

3. Primary Predicate Device Information

Manufacturer: W&H Dentalwerk Buermoos GmbH
Device: Cordless ENDO-Handpiece "ENTRAN" (W&H)
Cordless ENDO-Handpiece "S5 ENDO Motor
510(k) number: K090931

4. Device Description

Cordless endo motor is a professional equipment for root canal preparation. It is a drive for contra angle headpiece which is designed to assist dentists and dental surgeons perform standard endodontic procedures.

The endo motor consists of Cordless main unit, Charger station and Adapter. It is intended to use with FDA cleared contra-angle handpiece (transmission ratio of contra angle handpiece: 16:1) which would hold the drill bit or file. However the device do not included the contra angle handpiece and files.

The Endo smart is equipped with rechargeable Li-ion battery, which can be recharged using the provided charge station. By means of the different buttons on the main unit, the user could control various functions in the device, such as On/off, Speed, Torque and auto-reverse/auto forward mode.

The Endo motor is not sterile and cannot be autoclaved.

5. Intended Use/ Indication for Use

Endo Motor T-Fine-II is indicated for use in standard endodontic procedures using rotary endodontic files for mechanical and rotary preparation of the root canal.

6. Test Summary

ENDO Motor had been evaluated for its safety and performance by lab bench testing according to the following standards:

- ***Electrical safety and electromagnetic compatibility (EMC)***

Electrical safety and EMC testing were conducted on the subject device, and was found to comply with IEC 60601-1 and 60601-1-2, IEC80601-2-60.

Detail standard lists is as below items:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005+A1:2012
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests, 2014
- IEC 80601-2-60:2012 Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment

*Cleaning and Disinfection validation was conducted according to AAMI TIR30 and AAMI TIR12.

- **Software Verification and Validation Testing**

Software verification and validation testing were conducted and its documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was determined to be of "moderate" level of concern.

7. Clinical Testing

Clinical data were not required in this submission to support a finding of substantial equivalence.

8. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.

Item	Subject Device	Predicate Device	Remark
Name and mode	Endo Motor, T-Fine-II	Cordless ENDO-Handpiece "ENTRAN" (W&H)	--
510K number	K192649	K090931	-
Manufacturer	Foshan CICADA Dental Instrument Co., Ltd	W&H Dentalwerk Buermoos GmbH	-
Intended Use	Endo Motor T-Fine-II is indicated for use in standard endodontic procedures using rotary endodontic files for mechanical and rotary preparation of the root canal.	Modular electrical system for mechanical preparation of the root canal, using a special root canal instrument, which is intended by the manufacturer for use in the mechanical and rotary preparation of the root canal.	Minor difference Note 1:
Rx or OTC	Rx	Rx	Same
Physical Attributes			
Weight	200g	120g	Minor difference; Note 2
Displayed Parameters	Speed/Ratio, Torque, Volume, Antomatic control mode,	Torque, Speed	Minor Different, Note 3
Other displayed information	Program number, Power display	Power display	Minor Different, Note 3
Electrical Power			
DC Mains	AC100~240V 50/60Hz Output voltage: 5Vdc Output current: 1A	AC100~240V 50/60Hz Output voltage: 5Vdc Output current: 1A	Minor difference Note 4
Battery	Battery Voltage: 3.7Vdc	Battery Voltage:	

	Battery capacity: 1050mAh	3.7Vdc Battery capacity: 680mAh	
Environmental Operation			
Temperature	10~40℃	0~40℃	Minor difference Note 5
Humidity	<80%RH	15%~80%	
Environmental Storage			
Temperature	-40℃～55℃	-40℃～70℃	
Humidity	<80%RH	8%~80%	
Performance			
transmission ratio of electric contra angle	16:1	16:1	Same
Torque	0.3-3.0 Ncm	0.5-4.0 Ncm	Minor difference Note 6
Auto-control mode	Yes	Yes	Same
Funtion can be settable	Speed, Torque, and Auto-control setting	Speed, Torque and Auto-control setting	Same
Lubricant for motor	N/A	N/A	Same
Material			
Enclosure of Main unit	ABS	ABS	Same
Performance standard			
Standard	AAMI/IEC60601-1 IEC60601-1-2 IEC 80601-2-60:2012	IEC60601-1; IEC60601-1-2	Same
Device shape			
Outlook appearance	Portable	Portable	Same

Note for Detailed comparison

1. For the statement of intended use, even there is only minor difference on the words for indented use, but its meaning of the description So it has the same intended use as the predicate device (K090931).

2. There is difference of the weight between T-Fine-II and the predicate device. That is because the appearance of T-Fine-II is different from the predicate device, but the design of subject device comply with electrical safety standard IEC/AAMI 60601-1, so the minor difference would not affect its safety and

effectiveness.

3. The displayed parameters of T-Fine-II are different from the predicated device, but the design of subject device comply with electrical safety standard IEC/AAMI 60601-1 and display function had been validated in software evaluation report, so the minor difference would not affect its safety and effectiveness.
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4. There is minor difference on the battery capacity from 1050mAh to 680mAh, but the design of subject device comply with electrical safety standard IEC/AAMI 60601-1, so the minor difference would not affect its safety and effectiveness.

5. There is minor difference on storage temperature and humidity of T-Fine-II, comparing with the predicate device, the device shall be stored according to the specified environment, so that it do not affect the function of the device. So the minor difference would not affect its safety and effectiveness.

6. Even there is minor difference on the torque setting range, however it is adjustable in the main unit by dentist operator, the device provide with auto reverse and stop function when motor bear the torque resistance higher than the setting torque; and the device comply with IEC80601-2-60 Requirement. So such minor difference would not affect its safety and effectiveness

Conclusion

The subject device Endo motor has all features of the predicate device for intended use. Thus, the subject device is substantially equivalent to the predicate device.

9. Summary Prepared Date

10 Mar 2021