Foshan CICADA Dental Instrument Co, Ltd.
℅ Jet Li
Manager
Guangzhou KEDA Biological Technology Co., Ltd
6F, No.1 TianTai Road, Science City, LuoGang District
Guangzhou, Guangdong 510010
CHINA

Re: K202075
Trade/Device Name: Dental Electric Motor
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: February 12, 2021
Received: February 14, 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 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)*
K202075

Device Name
Dental Electric Motor

Indications for Use *(Describe)*
Dental Electric Motor NL400-1 is intended to convert pneumatic output from a dental treatment center to electrical energy to drive an electric micro motor and to operate electrically- driven dental handpieces.it is for use in general dental applications with use of a straight, right-angle or contra-angle, ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed. This system is designed for use by a trained professional in the field of general dentistry.

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

K202075

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 872.6070, and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: *Foshan CICADA Dental Instrument Co, Ltd*
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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
- Classification Name: Dental Handpiece and Accessories
- Trade Name: Dental Electric Motor
- Model: NL400-1
- Review Panel: Dental
- Product Code: EBW
- Regulation Number: 21 CFR 872.4200
- Regulation Class: 1

3. Predicate and Reference Devices Information

Predicate Device

- Sponsor: Nakanishi, Inc.
- Classification Name: Dental Handpiece and Accessories
- Trade Name: A-dec NLZ Electric Motor System
- 510(k) number: K163131
- Review Panel: Dental

- Product Code: EBW
- Regulation Number: 21 CFR 872.4200
- Regulation Class: 1

Reference Device

- Sponsor: HANDPIECE HEADQUARTERS.
- Classification Name: Dental Handpiece and Accessories
- Trade Name: Maxima Electric System
- 510(k) number: K180845
- Review Panel: Dental
- Product Code: EBW
- Regulation Number: 21 CFR 872.4200
- Regulation Class: 1

4. Device Description

Dental Electric Motor NL400-1 is a system attached to dental treatment center to operate electrically driven low speed handpieces. It consists of the components Control Unit, Micromotor, Motor Cable, and AC Adaptor. The common gear ratio is 1:1, 16:1 and 1:5, the speed range is from 2000 to 40,000 rpm.

The Control Unit provides the operation panel to achieve different operation functions, such as turn on/off the motor, adjust the motor speed, select memory setting, choose the motor work ratio, and the motor rotate direction.

The Motor Cable is connected to the Control Unit and the Micromotor, and contains lead wires to power the motor and tubing to transmit air/water/spray provided and controlled by the dental treatment center.

The Micromotor is built in with a three-phase DC motor and an LED light, and contains air and water outlet, which can drive the electrically-driven handpiece with the set output parameters and transmits the air/water/spray and lights.

Indications for UseDental Electric Motor NL400-1 is intended to convert pneumatic output from a dental treatment center to electrical energy to drive an electric micro motor and to operate electrically- driven dental handpieces. It is for use in general dental applications with use of a straight, right-angle or contra-angle, ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed. This system is designed for use by a trained professional in the field of general dentistry.

5. Test Summary

Dental Electric Motor has been evaluated the safety and performance by lab bench testing according to the following standards:

- ☒ IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+ A12)
- ☒ 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
- ☒ ISO 14457, Dentistry - Handpieces and motors, First edition 2012-09-15
- ☒ Moderate level of software documentation and verification per the FDA Guidance Document for Software Contained in Medical Devices
- ☒ Sterilization and cleaning validation per ISO 17665-1, and FDA Guidance Document for Reprocessing of Medical Device
- ☒ 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

6. 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.

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Verdict
Manufacturer	*Foshan CICADA Dental Instrument Co, Ltd*	Nakanishi, Inc.	Handpiece Headquarters - HPR Inc	--
Product Name	Dental Electric Motor	A-dec NLZ Electric Motor System	Maxima Electric System	--
510K number	TBD	K163131	K180845	--
Classification Name	Dental Handpiece and Accessories	Dental Handpiece and Accessories	Dental Handpiece and Accessories	--
Regulation Class	Class Ⅰ	Class Ⅰ	Class Ⅰ	--
Product Code	EBW	EBW	EBW	--
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	--
OTC & Rx	Rx	Rx	Rx	--
Indications for Use				

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Verdict
Indications for Use	Dental Electric Motor NL400-1 is intended to convert pneumatic output from a dental treatment center to electrical energy to drive an electric micro motor and to operate electrically- driven dental handpieces.it is for use in general dental applications with use of a straight, right-angle or contra-angle, ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed. This system is designed for use by a trained professional in the field of general dentistry	The A-dec NLZ electric motor system is comprised of a control unit that drives a direct current (DC) electric micromotor that is activated by means of a foot control. It is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment, with use of a straight, right-angle or contra-angle ISO E-type handpiece attachment of equal, gear-reducing, or gear-increasing speed.	The Maxima Electric System is intended to convert pneumatic output from a dental treatment center to electrical energy to drive an electric micro motor and to operate electrically- driven dental handpieces. This system is designed for use by a trained professional in the field of general dentistry.	SE Note 1
Device Design				
Drive Type	Electronic-micromotor	Electronic-micromotor	Electric micromotor	SE
Output voltage of adapter	DC 24V	DC 24V	36V	SE
Mainly Components	Control unit, Motor, Motor cable Adapter	Motor controller, Electric micromotor, Motor tubing	Motor controller, Electric micromotor, Motor tubing, Adapter	SE Note2
Dimensions	Control Unit: L130×W120×H48mm Motor cable: 92cm Micromotor: L103×Φ15.7mm, tubing length 1530mm	Motor controller: D78.5×W148.0×H43.0mm Motor Length: 31 mm Motor Diameter: Φ20.1(Front) Φ22.1(Rear) Motor tubing length: NLZ CDAS: 1600mm NLZ CDAL: 2080mm	/	SE Note2
Coolant mechanism	Coolant air	Coolant air	/	SE
Function	Motor start/stop	Motor rotation/stop, speed	Speed control, Torque	SE

Elements of Comparison	Subject Device	Predicate Device	Reference Device	Verdict
	Rotation speed setting Rotation direction setting Rotation ratio setting Recorded rpm memory	setting value, torque setting value, and LED turning ON/OFF, instructed rotation speed and torque, standard mode and endo mode	control, Program Memory	Note3
Allow of Foot switch to control	YES	YES	YES	SE
Internal irrigation	Yes	/	Yes	SE
Composition of Materials				
Motor exterior/Interior	Stainless Steel	Titanium	Stainless Steel	SE
Motor Cable/Air and water channel	Silicone rubber/PU Rubber	-	Silicone rubber	SE Comply with ISO 10993-1
Light	LED	LED	LED	SE
Technical Specifications				
Range of rotation speed	2000-40000rpm	standard mode: 1,000-40,000 rpm endo mode: 100-5,000 rpm	100-40,000rpm	SE Note 3
Speed Ratio	16:1, 1:1, 1:5	/	1:5, 1:1	SE Note3
Rotating direction	Forward and Reverse	Forward and Reverse	/	SE
Maximum Torque	4.20 N*cm(Stall torque)	4.00 N*cm(Stall torque)	/	SE Note4
Torque Range	1-3.0 N*cm	0.30-3.00 N*cm	3.0 N*cm	SE Note4
Sterilization	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	SE
Available Handpiece type	E-type (ISO3964)	E-type (ISO3964)	E-type (ISO3964)	SE
FDA-Recognized Standards				
Electrical safety, EMC	IEC 60601-1 IEC 60601-1-2 ISO 14457	IEC 60601-1 IEC 60601-1-2 ISO 14457	IEC 60601-1 IEC 60601-1-2 ISO 14457	SE

Note 1

Although there is little difference for illustration about the indication for use, the description of the predicate device is more specified, yet their meanings are the same. This difference does not affect the safety and effectiveness.

Note 2

Although the subject device has a motor build-in a connecting tube, and the control unit of predicate device is contained within external delivery system, the design and functions of subject device are mainly equivalent to the predicate device and reference device. The differences do not affect the safety and effectiveness.

Note 3

Although the Speed and gear ratio of subject device are little different to the predicate devices, the subject device is compiled with ISO 14457. And the subject device provides 16:1 gear ratio to transfer the handpiece speed to lowest speed of 100 rpm. So the minor differences do not affect the safety and effectiveness

Note 4

Although the subject device has not provided torque control, the stall torque of electric mircomotor is similar to the predicate device, the differences do not affect the safety and effectiveness.

7. Summary for clinical test

Clinical performance is not deemed necessary.

8. Conclusion

The subject device Dental Electric Motor has all features of the predicate device and reference device for intended use. Thus, the subject device is substantially equivalent to the predicate device.

9. Summary Prepared Date

Mar 3, 2022