January 13, 2022

Guilin Woodpecker Medical Instrument Co., Ltd.
℅ Field Fu
Senior Consultant
Shenzhen Joyantech Consulting Co., Ltd.
Block A, Zhongguan Times Square, Liuxian Avenue,
Xili Town, Nanshan District
Shenzhen, Guangdong
CHINA

Re: K203706
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, EGS
Dated: December 7, 2021
Received: December 20, 2021

Dear Field Fu:

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)*
K203706

Device Name
Dental Electric Motor

Indications for Use *(Describe)*
The MT2 dental electric motor consists of main unit, motor, motor tail, power adapter and power cord. 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. The Dental Electric Motor can be used with ISO E-type a straight, right-angle or contra-angle handpiece attachment of equal, gear-reducing, or gear increasing speed.
The contra-angle handpieces (model:WJ-15, WJ-15L) are driven by a micro-motor to rotate at a specified speed, so as to drive the dental bur. It is applicable to drilling and grinding in dental surgery.

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

K203706

This summary of 510(K) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

5.1 Administrative Information

Date of Summary prepared	January 11, 2022
Manufacturer information	Company title: Guilin Woodpecker Medical Instrument Co., Ltd. Company address: Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004, China Contact person: Jiakang Ning Phone: +86 7735873198 Fax: +86-7735822450 E-mail:zmnbg03@glwoodpecker.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Mr. Field Fu E-Mail:field@cefda.com;
Establishment registration number	3005581016

5.2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Dental Electric Motor
Model:	MT2
Classification name:	Controller, Foot, Handpiece and Cord
Regulation Name:	Dental Handpiece and Accessories

Review Panel:	Dental
Product Code:	EBW
Additional Product Code:	EGS
Device Class:	I
Regulation Number:	872.4200

5.3 Predicate Device Information

Primary predicate device	
Sponsor:	Nakanishi, Inc.
Device:	A-dec NLZ electric motor system
510(K)Number:	K163131
Reference device	
Sponsor:	Nakanishi, Inc.
Device:	General Cutting Contra Handpiece
510(K)Number:	K182999

5.4 Device Description

The MT2 dental electric motor consists of main unit, motor, motor tail, power adapter and power cord. 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 handpiece attachment of equal, gear-reducing, or gear increasing speed.

Dental Electric Motor (model: MT2) is a control unit, which is connected to an AC power supply and a handpiece hose, that drives a DC electric micromotor, and turns on or off or regulates the speed of the motor by the foot control of the dental unit. The foot switch is not included in the control unit. It is used together with a handpiece attachment. It provides a low voltage DC power supply for the handpiece attachment with light.

The device is for prescription use.

5.5 Indications for Use

The MT2 dental electric motor consists of main unit, motor, motor tail , power adapter and power cord. 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. The Dental Electric Motor can be used with ISO E-type a straight, right-angle or contra-angle handpiece attachment of equal, gear-reducing, or gear increasing speed.

The contra-angle handpieces (model: WJ-15, WJ-15L) are driven by a micro-motor to rotate at a specified speed, so as to drive the dental bur. It is applicable to drilling and grinding in dental surgery.

5.6 Technological characteristics of the subject device compared to the predicate device

Comparison to predicate device:

Item	Subject Device	Primary Predicate Device(K163131)	Reference device(K182999)	Remarks
Product Code	EBW, EGS	EBW	EGS	Identical
Regulation No.	872.4200	872.4200	872.4200	Identical
Class	I	I	I	identical
Indication for use	The MT2 dental electric motor consists of main unit, motor, motor tail, power adapter and power cord. 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. The Dental Electric Motor can be used with ISO E-type a straight, right-angle or	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	The General Cutting Contra Handpiece is powered by either an air-motor or electric micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown	Similar (Discussion 1)

Item	Subject Device	Primary Predicate Device(K163131)	Reference device(K182999)	Remarks
	contra-angle handpiece attachment of equal, gear-reducing, or gear increasing speed. The contra-angle handpieces (model:WJ-15, WJ-15L) are driven by a micro-motor to rotate at a specified speed, so as to drive the dental bur. It is applicable to drilling and grinding in dental surgery.	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.	preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.	
Dental electric Motor				
Drive	Electric-micromotor	Electric-micromotor	NA	Identical
Components	Main unit, DC adapter, DC cord, motor, motor tail	Motor controller, Electric micromotor, Motor tubing	NA	Identical
Power source	AC/DC Adapter: Power supply input:100-240Vac, 50/60Hz, 2.5A Power supply output: DC30V, 3.0A	---	NA	---
Size	**Main unit:** W165.5 x D129.7 x H77.6mm **Motor:** DΦ22 x H76.7mm **Motor tail:** Length: 1800mm	**Motor controller:** D78.5 x W148.0 x H43.0mm **Motor:** Length: 31mm, Diameter: Φ20.1(Front), Φ22.1(Rear) **Motor tubing:** Length: NLZ CDAS: 1600mm NLZ CDAI: 2080mm	NA	Different (Discussion 2)
Material of Motor exterior	Aluminum alloy	Titanium	NA	Different (Disc

Item	Subject Device	Primary Predicate Device(K163131)	Reference device(K182999)	Remarks
				ussion 2)
Light	LED	LED	NA	Identical
Rotation Speed	2,000-40,000 rpm	1,000 - 40,000 rpm	NA	Similar(Discussion 2)
Rotation direction	Forward and reverse	Forward and reverse	NA	Identical
Coolant mechanism	Coolant air	Coolant air	NA	Identical
Available Handpiece type	E-type (ISO 3964)	E-type (ISO 3964)	NA	Identical
Usage environment	Temperature: 5-40°C, Humidity: 30-75%	Temperature: 0 - 40°C, Humidity: 30-75%	NA	Similar(Discussion 2)
Handpiece				
Operational modes	Air-power	NA	Air-power	Identical
Optical fiber	WJ-15: without light WJ-15L: with light	NA	With light, without light	Identical
Type of chuck	Mechanical type chuck	NA	Mechanical type chuck	Identical
Coupling dimensions	Middle (ISO 3964-2016)	NA	ISO 3964 (EN ISO 3964) Standard Coupling	Identical
Material of handpiece	Copper, Stainless steel	NA	Titanium	Different (Discussion 2)
Shanks for rotary instruments	Type3,Φ1.6mm drill (ISO 1797-1-2011)	NA	Type 1, Type 3	Identical

Item	Subject Device	Primary Predicate Device(K163131)	Reference device(K182999)	Remarks
Gear Ratio Max rotation speed (handpiece)	1:5 Increasing-200,000 min^{-1}	NA	16:1 Reduction-2,500 min^{-1} 10:1 Reduction-4,000 min^{-1} 4:1 Reduction-10,000 min^{-1} 1:1 Direct Drive-40,000 min^{-1} 1:5 Increasing-200,000 min^{-1}	Identical
Lubricant	NSK Pana-Spray (K052700)	NA	NSK PANA SPRAY Plus (K163483)	Identical
Sterilization	Sterilized by user (Steam sterilization)	Sterilized by user (Steam sterilization)	Sterilized by user (Steam sterilization)	Identical
Sterilization Validation Standard	ANSI/AAMI/ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical

Discussion 1: The predicate device is only a motor system, while the subject device includes a motor system and handpiece. Therefore, the intended use of the two is a little different. In order to be equivalent, we have added a reference device(K182999).

Discussion 2: In the comparison table, there are some differences between the subject device and the predicate device, such as the size and the materials of the device. We considered that the differences did not affect the identical principles of operation between the subject device and the predicate device. And the differences would not cause new risk to users and patients. Performance testing including Biocompatibility testing, Electric safety and EMC testing, bench testing was performed in order to demonstrate substantial equivalence to the predicate device. Also, sterilization validation and software validation were performed in accordance with FDA Guidance. The subject device met all the requirements of the standards. Therefore, the subject device demonstrated substantial equivalence to the predicate device.

Note1: DC adaptor meets IEC 60601-1 standard.

5.7 Brief discussion of the nonclinical tests

The subject device conforms to the following standards:

IEC 60601-1:2005+AM1:2012 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 Disturbances - Requirements And Tests

IEC 80601-2-60：2019 Medical Electrical Equipment - Part 2-60: Particular Requirements For The Basic Safety And Essential Performance Of Dental Equipment

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.

ISO 14457: 2017 Dentistry- Handpieces and motors.

Software Documentation of a MODERATE level of concern was provided per FDA Software Guidance titled: “Guidance for Industry and FDA Staff- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Cleaning and Sterilization Validation of the Contra-Angle and Motor and High-Level Disinfection Validation for the Motor Tubing were provided per FDA Reprocessing Guidance titled: “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff.

5.8 Brief discussion of clinical tests

N/A.

5.9 Other information (such as required by FDA guidance/Test)

The FDA Dental Handpiece Guidance titled: “Guidance for Industry and FDA Staff – Dental Handpieces – Premarket Notification [510(k)] Submissions,” available at https://www.fda.gov/media/71432/download.

5.10 Conclusions

The differences between subject device and predicate/reference devices do not affect the safety and effectiveness of the subject devices.
Thus, the subject device is substantially equivalent to the predicate device.