November 21, 2022

Guilin Woodpecker Medical Instrument Co., Ltd.
% Fu Ailing
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Liuxian Avenue, Xili Town Nashan District
Shenzhen, Guangdong 518055
CHINA

Re: K211358
Trade/Device Name: Implanter incl. Accessories
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: October 25, 2022
Received: October 25, 2022

Dear Fu Ailing:

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 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)*
K211358

Device Name
Implanter incl. Accessories

Indications for Use *(Describe)*
Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.

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 – K211358

This 510(k) Summary is submitted according to the requirements of 21 CFR §807.92.

5.1 Administrative Information

Date Summary prepared	November 17, 2022
Manufacturer information	Submitter's Name: Guilin Woodpecker Medical Instrument Co., Ltd. Address: Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004, P.R. China Contact person: Yang Yunfeng TEL: +86-773-2350532 FAX: +86-773-5822450 Mail: ipr@glwoodpecker.com
Submission Correspondent	Company Name: Shenzhen Joyantech Consulting Co., Ltd. Address: Room 1713A, 17 Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong, 518055, China Contact person: Ms. Fu Ailing E-Mail: aileen@cefda.com
Establishment registration number	3005581016

5.2 Device Information

Type of 510(k) submission:	Traditional
Common Name:	Controller, Foot, Handpiece and Cord
Trade Name:	Implanter incl. Accessories
Model:	Implanter
Classification name:	Dental Handpiece and Accessories

Review Panel:	Dental
Product Code:	EBW
Device Class:	I
Regulation Number:	21 CFR 872.4200

5.3 Predicate Device

Predicate Device

Sponsor:	W&H DENTALWERK BÜRMOOS GMBH
Device:	Implantmed SI-1015 incl. Accessories
510(K) Number:	K161957

Reference Device

Sponsor:	W&H Dentalwerk Buermoos GmbH
Device:	ImplantMED SI-915 (115V Version) ImplantMED SI-923 (230V Version) Incl. Accessories
510(K) Number:	K052741

5.4 Device Description

The Implanter is intended for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.

The submission consists of:

- the control unit
- a motor with cable with light (sterilizable: SPM58L)
- a wired foot control (MF4)
- and as an attachment the surgical contra-angle handpieces (with LED:WP-1L/without LED:WP-1)

Eight different programs can be selected by the user. Switching between these programs is performed by foot control or via touch display.

The programs include Positioning, Hole-drilling, Hole-Broadening, Tapping, Implanting, Lock the Abutment Screw, User Defined Mode and Cleaning.

The control unit is intended to be used with the motor SPM58L.

To run the Implanter according to its intended use, Guilin Woodpecker provides two different **surgical handpieces**.

Type	Transmission ratio	Max. speed	Max. torque
WP-1L	20:1	40,000	80 Ncm
WP-1	20:1	40,000	80 Ncm

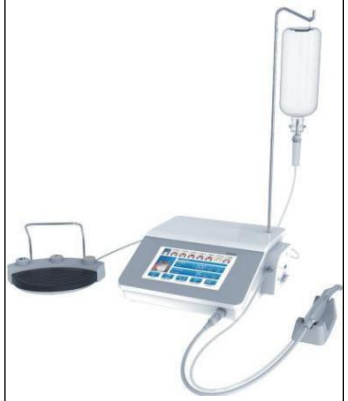
5.5 Indications for Use

Implanter (incl.SPM58L):

Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.

5.6 Indication for Use and Technological Characteristics of the Subject Device Compared to the Predicate Device

Table 1 Comparison of Indications for Use and Technological Characteristics Between the Subject Device and the Predicate Device

General Specification Implanter incl. Accessories					
ID	**Comparison Item**	**Proposed Device Implanter incl. Accessories**	**Predicate Device Implantmed SI-1015 incl. Accessories K161957**	**Reference Device ImplantMED SI-915 (115V Version) ImplantMED SI-923 (230V Version) Incl. Accessories K052741**	**Difference Between the Proposed Device and the Predicate Device**
1	Picture				-
2	Name	Implanter	Implantmed SI-1015	Implantmed SI-915/923	-
3	Manufacturer	Guilin Woodpecker Medical Instrument Co., Ltd.	W&H Dentalwerk Bürmoos GmbH	W&H Dentalwerk Bürmoos GmbH	-

4	Where Used	Dental practice, dental clinic	Dental practice, dental clinic	Dental practice, dental clinic	None
5	Indication for Use	Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.	Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.	Mechanical drive unit with coolant supply for transmission instruments with coupling system according to ISO 3964 (Din 13.940) The equipment is a drive unit for use in dental surgery, implantology and maxilla-facial surgery for treatment of dental hard tissue.	None
6	Control Unit	Main dimensions: 276x267x110 mm Front panel: Display with capacitive touch Programs: 8 programs for various	Main dimensions: 100x262x291 mm Front panel: Display with capacitive touch Programs: 5 programs for various	Main dimensions: 90x252x254mm Front panel: Graphical display without backlighting Programs: 5 programs for various	Yes. For Guilin Woodpecker Medical Instrument Co., Ltd., there are 8 programs: 1. Positioning, 2. Hole-drilling, 3. Hole-Broadening, 4. Tapping,

		stages of implantology Irrigation: 110ml/min. Irrigation Tubing can be inserted ergonomically on the unit's side face	stages of implantology Irrigation: 100ml/min. Irrigation Tubing can be inserted ergonomically on the unit's side face	stages of implantology Irrigation: 100ml/min. Irrigation Tubing can be inserted on the unit's front face	5. Implanting, 6. Lock the abutment screw, 7. User defined Mode, 8. Cleaning For W&H Dentalwerk Bürmoos GmbH, there are 5 programs: Drill function, Drill function, Drill function, Thread-cutter function, Implant insertion. Similar functions include: 2 vs a or b or c; 4 vs d; 5 vs e. The additional programs included for the proposed device include 1,3,6,7 and 8. 1 – Includes set ranges of speed and torque for positioning of implant placement.

					3 – Includes set ranges of speed and torque for hole-broadening procedures. 6 – Includes set ranges of speed and torque for placement of the abutment screw. 7 – User defined mode for use with a straight handpiece with ball drill bit. 8 – Used to adjust the water capacity. Differences between functions are supported by performance testing.
7	Foot Control	Main dimension: 249.7x181.7x160.8 Features: 4 buttons for pump on/off Forward/reverse Change programs	Main dimension: 154x202x210 Features: 4 buttons for pump on/off Forward/reverse Change programs	Main dimension: 215x190x40 (without cable) Features: 4 buttons for pump on/off Forward/reverse Change programs	Yes. The power supply of the proposed device is performed via wired foot control not via wireless control. The reference device also includes a wired foot control.

		Motor control (on/off and variable) Power supply: Wired Via cable	Motor control (on/off and variable) Power supply: Wireless Via 3xAA batteries	Motor control (on/off and variable) Power supply: wired via cable	
8	Motor with Cable	Length: 110 mm With LED contacts without LED contacts	Length: 71.65 mm With LED contacts	Length: 75 mm Without LED contacts	Yes. The motor is with LED contacts or without LED contacts. The predicate device includes LED contacts and the reference device includes no LED contacts.
9	Module	/	W&H SI-SQ: Connection via USB-cable	Osstell ISQ: Stand-alone device	Yes. The proposed device does not include a module. However, performance testing has been included demonstrating its use.

Technical Data/Functions Implanter incl. Accessories					
ID	**Comparison Item**	**Proposed Device Implanter incl. Accessories**	**Predicate Device Implantmed SI-1015 incl. Accessories**	**Reference Device ImplantMED SI-915 (115V Version) ImplantMED SI-923 (230V Version) Incl. Accessories**	**Difference Between the Proposed Device and the Predicate Device**
10	Max. Mechanical output power	120 W	80 W	70 W	Yes. Due to different design scheme, the proposed device has the higher power, but this does not lead to any negative effect regarding substantial equivalence because of the constructive power reserves of the motor (no big difference between 5.5 Ncm – 6.2 Ncm for the motor).
11	Torque at the motor	5.5 Ncm	6.2 Ncm	5.5 Ncm	Yes. The proposed device offers a lower maximum level of torque output at the motor: 5.5 Ncm. However, this is in alignment with the reference device.

12	Speed range of motor	300 - 40,000 rpm	200 - 40,000 rpm	200 - 40,000 rpm	None
13	Supply voltage	100-120 VAC	100-130 VAC	100-130 VAC	None
14	Rated current	1.5-2 A	0.3-1.6 A	0.2-1.6 A	Yes. This does not affect substantial equivalence according to performance testing.
15	Frequency	50-60 Hz	50-60 Hz	50-60 Hz	None
Material					
ID	**Comparison Item**	**Proposed Device Implanter incl. Accessories**	**Predicate Device Implantmed SI-1015 incl. Accessories**	**Reference Device ImplantMED SI-915 (115V Version) ImplantMED SI-923 (230V Version) Incl. Accessories**	**Difference Between the Proposed Device and the Predicate Device**
16	Control unit housing	Plastic material	Plastic material	Plastic material	None
17	Tubing outer shealth	Customer specific	Customer specific	Customer specific	None

18	Motor with cable	Stainless Steel, Aluminum Alloy (Motor) and Silicone, Silicone dioxide, Polydimethylsiloxane (Cable)	Stainless steel	Stainless steel	Yes. This does not raise any additional questions regarding substantial equivalence according to testing conducted per ISO 10993.
19	Surgical handpieces	Chromium plated steel and chromium coated brass	Chromium coated steel and chromium coated brass	Chromium coated steel and chromium coated brass	Yes. This does not raise any additional questions regarding substantial equivalence according to testing conducted per ISO 10993.
20	Module	/	Stainless steel	Stainless steel	Yes. The proposed device does not include a module. Therefore, material composition is not applicable.
Hygiene/Maintenance **Surgical Handpieces WP-1L/WP-1, Motors SPM58L, and others**					

ID	Comparison Item	Proposed Device Implanter incl. Accessories	Predicate Device Implantmed SI-1015 incl. Accessories	Reference Device ImplantMED SI-915 (115V Version) ImplantMED SI-923 (230V Version) Incl. Accessories	Difference Between the Proposed Device and the Predicate Device
21	Lubrication	After max. 30 minutes of use SPM58L: No lubrication is needed	After max. 30 minutes of use EM-19 LC/EM-19: No lubrication is needed	After max. 30 minutes of use Motor with cable: No lubrication is needed	None
22	Cleaning	Rinse under distilled water or deionized water (<45 ℃/113℉) with a soft cloth	Rinse under demineralized water (< 38 ℃/100℉) with aid of brush	Rinse under demineralized water (< 38°C/100°F) with aid of brush	Yes. This does not affect substantial equivalence according to reprocessing validation.
23	Disinfection	Wiping disinfection using disinfectant cloths	Wiping disinfection using disinfectant cloths	Wiping disinfection using disinfectant cloths	None
24	Sterilization	Dynamic-air-removal sterilizers: 270 ℉ (132 ℃) for 4 minutes	Dynamic-air-removal sterilizers: 270 ℉ (132 ℃) for 4 minutes or Gravity displacement sterilizers: 270 ℉ (132 ℃) for 15 minutes	Dynamic-air-removal sterilizers: 270°F (132°C) for 4 minutes or Gravity displacement sterilizers: 270°F (132°C) for 15 minutes	None. Same Sterilization Cycle Parameters for Dynamic-air-removal.

From above table, the proposed device and the predicate device have identical indications for use. Although there are subtle technological characteristic differences between the proposed device and the predicate device, the technological characteristic differences discussed do not affect the substantial equivalence.

5.7 Brief discussion of the non-clinical tests

To verify the performance requirements of the proposed device, the following tests were performed in accordance with listed standards and FDA guidance documents. Testing results demonstrate substantial equivalence.

- To verify the conformity of the proposed device with the requirements of IEC 60601-1:(*Medical electrical equipment Part 1: General requirements for basic safety and essential performance*).
- To verify the conformity of the proposed device with the requirements of IEC 60601-1-2:(*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic compatibility*).
- To verify the handpiece function and lifecycle according to ISO 14457:2017: (*Dentistry-Handpieces and Motors)*.
- To validate the proposed device's software and its foot control's software respectively in conformity with IEC 62304 (*Medical device software - Software lifecycle processes*) and FDA Guidance titled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" for a MODERATE level of concern.
- To verify the thermal safety in conformity with the standard IEC 62471:2004: *(Photobiological safety of lamps and lamp systems)*.
- To evaluate the biocompatibility of patient contacting components of the proposed device according to the requirements ISO 10993-1 *(Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process)*, ISO 10993-5 *(Biological evaluation of medical devices Part 5: Test for cytotoxicity)*, ISO 10993-10 *(Biological evaluation of medical devices - Part 10: Tests for skin sensitization)* and ISO 7405 (Dentistry - Evaluation of biocompatibility of medical devices used in dentistry).
- To verify the conformity of the proposed device with the requirements of IEC 60601-1-2:(*Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic compatibility*) and IEC 60601-1-1 *(Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems)*.
- To validate the reprocessing (Cleaning, Sterilization) according to FDA Guidance titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff,"
- To verify the conformity of the proposed device with the requirements of FDA Guidance on Dental Handpieces titled "Dental Handpieces – Premarket Notification [510(k)] Submissions.

5.8 Brief discussion of clinical tests

No clinical data is needed to demonstrate substantial equivalence.

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

N/A.

5.10 Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Guilin Woodpecker Medical Instrument Co., Ltd. concludes that:

- The indications for use of the proposed device is identical to that of the predicate device.
- The technological characteristic differences between the proposed device and the predicate device do not affect the substantial equivalence, so no new risk is raised.
- Demonstrated by the safety and performance tests, the characteristics of the proposed device are substantially equivalent to those of the predicate device.