April 11, 2025

Guilin AestheDent Medical Instruments Co., Ltd
% Salon Chen
System Engineer
IMD Medical & Drug technology service institutions
Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District
Dongguan, 523039
CHINA

Re: K242646
Trade/Device Name: Dental Implant Unit
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW,
Dated: March 17, 2025
Received: March 17, 2025

Dear Salon Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242646

Device Name

Dental Implant Unit

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

1. 510(k) Sponsor:

- Company Name: Guilin AestheDent Medical Instruments Co., Ltd.
- Address: 3rd Floor, Building 12th, Guilin Creative Industry Park, No. 70, Qilidian Road, Qixing District, Guilin City, Guangxi Province, 541004, P.R. China
- Phone: +86 13977319343
- Contact Person (Title): Wen Guofeng (General Manager)
- E-mail: 12073376@qq.com

- Date of Preparation: March 17, 2025

2. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person (Title): Salon Chen (System engineer)
- E-mail：33999439@qq.com
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China

3. Name of the Device:

- Name: Dental Implant Unit
- Model: IMPLANT surg

4. Common Name and Classification:

- Device Classification Name: Dental Handpiece and Accessories

- Classification Product Code: EBW
- Regulation Number: 872.4200
- Class: Class I
- Review Panel: Dental

5. Predicate Device Information:

- 510(k) Number: K231845
- Device Classification Name: Dental Handpiece and Accessories
- Sponsor: Guilin Woodpecker Medical Instrument Co., Ltd.
- Classification Product Code: EBW
- Regulation Number: 872.4200
- Class: Class I
- Review Panel: Dental
- Trade/Proprietary Name: Implanter incl. Accessories

6. Device Description

The Dental Implant Unit is intended for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue. The device is composed of main unit, motor with tube, handpiece, foot pedal and holder. 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.

7. Indications 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.

8. Comparison to the predicate device

8.1. Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	Guilin AestheDent Medical Instruments Co., Ltd.	Guilin Woodpecker Medical Instrument Co., Ltd.	/
Device Name	Dental Implant Unit	Implanter incl. Accessories	/
Regulation Description	Dental Handpiece And Accessories	Dental Handpiece And Accessories	SE
Review Panel	Dental	Dental	SE
Classification Product Code	EBW	EBW	SE
Regulation Number	872.4200	872.4200	SE
Class	Class I	Class I	SE
Prescription or OTC	Prescription Use	Prescription Use	SE
Environment of Use	Dental practice/ Dental clinic	Dental practice/ Dental clinic	SE

Intended 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.	SE

8.2. Table 2 Safety factor & Performance Comparison

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Software	Compliance with IEC 62304	Compliance with IEC 62304	SE
Biocompatibility	Compliance with ISO 10993-1	Compliance with ISO 10993-1	SE
Control Unit	Main dimensions: 286mm × 252mm × 113mm Front panel: Display with capacitive touch Programs: 8 programs for various stages of implantology Irrigation: 110ml/min. Irrigation Tubing can be inserted ergonomically on the unit's side face	Main dimensions: 276mm x 267mm x 110 mm Front panel: Display with capacitive touch Programs: 8 programs for various stages of implantology Irrigation: 110ml/min. Irrigation Tubing can be inserted ergonomically on the unit's side face	Different, Note1

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Foot control	Main dimension: 236mm x 168mm x 65mm Features: 4 buttons for pump on/off Forward/reverse Change programs Motor control (on/off and variable) Power supply: wired via cable	Main dimension: 249.7mm x 181.7mm x 160.8mm Features: 4 buttons for pump on/off Forward/reverse Change programs Motor control (on/off and variable) Power supply: wired via cable	Different, Note1
Motor with cable	Length: 108 mm With LED contacts	Length: 110 mm With LED contacts without LED contacts	Different, Note 1
Max. Mechanical output power	150W	120W	Different, Note 2
Torque at the motor	5.5 Ncm	5.5 Ncm	SE
Speed range of motor	200 - 40,000 rpm	300 - 40,000 rpm	Different, Note 3
Supply voltage	100-240VAC	100-120VAC	SE
Rated current	1.5-2A	1.5-2A	SE
Frequency	50-60HZ	50-60Hz	SE
Lubrication	After max. 30 minutes of Use Motor: No lubrication is needed	After max. 30 minutes of use SPM58L: No lubrication is needed	SE

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Cleaning, Disinfection & Sterilization	Required	Required	SE

8.3. Review of Differences:

Note 1 Dimensions Difference

The proposed device has slightly different dimensions on control unit, foot control, and motor cable length compared to the predicate device. Despite this, the usability compliance ensures that the subject device is safe and effective for its intended use. Furthermore, the subject device has demonstrated electrical safety by passing IEC 60601-1, IEC 60601-1-2, and IEC 80601-2-60 tests. Therefore, this difference does not affect the safety and effectiveness of the subject device compared to the predicate device.

Note 2 Dimensions Difference

The proposed device has a higher maximum mechanical output power (150 W) compared to the predicate device (120 W). This increase in power provides greater flexibility and efficiency during dental procedures, particularly when dealing with harder tissues or when more torque is required. Despite this, the proposed device has passed series of electrical safety and usability tests which demonstrates the enhanced power capacity simply offers improved performance without altering the device's fundamental operation or intended use. Therefore, this difference does not affect the safety and effectiveness of the proposed device compared to the predicate device.

Note 3 Motor speed range difference

The proposed device operates at a speed range of 200 - 40,000 rpm, whereas the

predicate device operates at 300 - 40,000 rpm. The lower starting speed allows for more precise control during delicate procedures, such as initial drilling or preparation stages where lower speeds are advantageous. The upper speed limit remains the same (40,000 rpm) for both devices, ensuring that the proposed device maintains the same high-speed capabilities as the predicate. The expanded speed range enhances the versatility of the device without compromising safety or effectiveness. Therefore, this difference does not affect the safety and effectiveness of the proposed device compared to the predicate device.

9. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The proposed device is the same as the predicate device but the two devices are different. A series of safety and performance tests were conducted on the subject device:

- Sterilization and Shelf Life & Packaging Test
- Biocompatibility
- Software Validation
- Electromagnetic Compatibility and electrical safety
- Function test

All the test results demonstrate the proposed device meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate device.

10. Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.