June 18, 2026

W&H Dentalwerk Buermoos GmbH
Weidler Gerhard
Regulatory Affairs Manager
Werner-Bader-Straße 1, 5111 Buermoos,
Salzburg, AUSTRIA

Re: K253776
Trade/Device Name: Implantmed Plus II & Piezomed Plus II Module
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZI, ELC, EBW
Dated: June 5, 2026
Received: June 5, 2026

Dear Weidler Gerhard:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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.

510(k) Number *(if known)*
K253776

Device Name
Implantmed Plus II & Piezomed Plus II Module

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

Piezomed Plus Module II:
Piezoelectric ultrasonic device, consisting of handpieces and associated instruments, intended for:
bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic, and surgical endodontic procedures.
Scaling applications are including:
- Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits,
- Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning,
- Endodontic: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha-condensation and retrograde preparation,
- Restorative and prosthetics: Cavity preparation, removal of prostheses, finishing of crown preparations.

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.

510(k) #: K253776

510(k) Summary

Prepared on: 2026-06-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	W&H Dentalwerk Buermoos GmbH
Applicant Address	Werner-Bader-Straße 1, 5111 Buermoos, Salzburg, Austria
Applicant Contact Telephone	+4362746236102
Applicant Contact	Dr. Weidler Gerhard
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Implantmed Plus II & Piezomed Plus II Module
Common Name	Bone cutting instrument and accessories
Classification Name	Drill, Bone, Powered
Regulation Number	872.4120
Product Code(s)	DZI, ELC, EBW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161957	W&H Implantmed SI-1015 incl. Accessories	EBW
K133488	Piezomed	DZI, ELC
K243280	Piezomed Pro	ERL, DZI, HW

Device Description Summary

21 CFR 807.92(a)(4)

The new Implantmed Plus II, types SI-2100, SI-2101 and SI-2102 Scan Edition (incl. the electric motor EM-19 LC and the wired/wireless foot controls S-N3/S-NW3) are intended for use in dental surgery, implantology and maxillofacial surgery (MF).
The new Piezomed Plus II Module, type SP-210M (including handpieces SA-40 and SA-40 L) is intended for the same treatment applications using ultra sonic technology for the treatment of hard tissue. The Module cannot be used without being connected to the new Implantmed Plus II device.
The new devices a redesigned versions of W&H's successor devices, the Implantmed SI-10xx (K161957) and the Piezomed SA-320 (K133488).
The basic function of the Implantmed Plus II is the conversion of electrical energy into a mechanical rotary motion. In addition, depending on the treatment, a physiological saline solution is pumped to the treatment site by a displacement pump. Via a control unit with electronics, the user can change the most crucial operating parameters within predetermined limits.
The electric motor with cable EM-19 LC has a connection according to ISO 3964 and can operate handpieces and contra-angle handpieces. The motor with cable needs to be attached to the motor control unit.
The medical device is activated or deactivated via a foot control.
The device settings and the treatment data generated by the device can be documented by the user via integrated documentation function.
In case of the SI-2102, used materials can also be integrated by code scanning to the treatment documentation.
The basic function of the Piezomed Plus II Module is the conversion of electrical energy into mechanical vibration. Using a control unit, the Implantmed Plus II, the user can change several operating parameters within predefined limits.

The Piezomed is activated or deactivated via a foot control.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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

Piezomed Plus Module II:
Piezoelectric ultrasonic device, consisting of handpieces and associated instruments, intended for:
bone cutting, osteotomy, osteoplasty and drilling in a variety of oral surgical procedures, including implantology, periodontal surgery, surgical orthodontic, and surgical endodontic procedures.
Scaling applications are including:
- Scaling: All general procedures for removal of supragingival and interdental calculus & plaque deposits,
- Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning,
- Endodontic: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha-condensation and retrograde preparation,
- Restorative and prosthetics: Cavity preparation, removal of prostheses, finishing of crown preparations.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use statements of the new W&H devices, Implantmed Plus II and the Piezomed Plus II Module, and the predicate W&H devices, Implantmed SI-10xx and Piezomed SA-320, are identical.

Technological Comparison 21 CFR 807.92(a)(6)

The new device, Implantmed Plus II, is the successor product of the predicate Implantmed SI-10xx (K161957) device and shares the same technological characteristics (design, basic materials, operation principle and energy source).

The new Piezomed Plus II Module is a modular device which can be only used with the new Implantmed Plus II device. It is the successor product of W&H's stand-alone device, the Piezomed SA-320 (K133488) and shares the same technological characteristics as the Piezomed SA-320 and the reference device, the Piezomed Pro Module (K243280).

Similarities:
The Implantmed is a surgical dental treatment system. It transmits power via an identical electric motor to compatible surgical handpieces and controls their functions. The integrated software can control functions such as brightness, direction of rotation, speed, and torque. The new Implantmed device shares these technical characteristics with the predicate device.

The Piezomed is an ultrasonic surgical dental treatment unit, which transmits power to a piezo handpiece and controls its functions. These technological characteristics are also shared with the predicate device.

Both devices can be used with a wired or wireless foot control. The new foot controls are identical in its technological characteristics and functions to the predicate foot controls.

Differences:
The differences of the new Implantmed device to its predicate device are the possibility to be cloud connected via integrated WiFi-technology, the new display and the light guide functions. Additionally, the Implantmed Plus II type SI-2102 has an included scan function for bar code reading to archive used materials or consumables.

The Piezomed Plus II Module can only be used together with the new Implantmed Plus II device and is no stand-alone device. Therefore, it uses the interface of the new Implantmed Plus II device.
Both devices (new device compared to the Piezomed SA-320, K133488), also considering the characteristics of the reference device (Piezomed Pro, K243280), share the same technological characteristics and the differences do not affect the safety and effectiveness. The difference in the dimensions of the module is more a matter of the modular approach, which does not affect substantial equivalence.

The differences of the Implantmed “System” do not affect substantial equivalence.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical Testing to Support Submission:

The aim of the evaluation was to demonstrate SE of the new devices and the selected predicate devices in terms of performances.
To verify the performance requirements of the proposed device, the following tests were performed in accordance with standards and FDA guidance documents. All tests were completed successfully.

Electromagnetic Compatibility and Electrical/Thermal Safety testing according to IEC 60601-1 "Medical electrical equipment Part 1: General requirements for basic safety and essential performance", IEC 80601-2-60 "Particular requirements for the basic safety and essential performance of dental equipment" and IEC 60601-1-2 "Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance Collateral Standard: Electromagnetic compatibility" were performed and show that the new devices are in compliance with these standards.

To verify the functions of the Piezomed handpieces tests according to ISO 18397 "Dentistry — Powered scaler" were performed.

Verification of the thermal safety in conformity with the standard IEC 62471 "Photobiological safety of lamps and lamp systems was performed.

Validation of the software functions of the new devices in conformity with IEC 62304 "Medical device software - Software lifecycle processes" and FDA Guidances titled "Content of Premarket Submissions for Device Software Functions", "General Principles of Software Validation", "Off-The-Shelf Software Use in Medical Devices" and "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" were performed.

A biocompatibility evaluation of patient contacting components of the proposed devices 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", ISO 10993-18 "Biological evaluation of medical devices – Part 18: Chemical characterization of materials", ISO 10993-23 "Biological evaluation of medical devices – Part 23: Tests for irritation" and ISO 7405 "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry" was conducted.

Reprocessing validation (Cleaning, Sterilization) according to FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" was performed.

Additional performance tests of the new Piezomed device for comparison with the predicate device and for determining that the new device functions as specified were performed. All tests were completed successfully.
These tests include the type test according to ISO 18397 of the SA-320 device (e.g. for parameters as coolant liquid supply, temperature rise, vibrations, tip performance, frequency characteristic and amplitude), sound level tests of the "Implantmed System" according to ISO 18397/ISO 14457 to ensure that the new device does not exceed the sound level of 80dB(A), life time tests of the user interface and irrigation pump, climate tests, drop tests according to ISO 2248, life time tests for tip change cycles and mating cycles for the connection between the Piezomed Module and the Piezomed handpiece.

Additional tests for the Piezomed tips, which are identical to the predicate device, were performed to confirm:
- The performance with respect to the new device;
- The requirements on amplitude and frequency;
- Irrigation water flow rate;
- The tuning frequency of the inserts is between 22 and 35 kHz, which is the range of the device functional ultrasonic frequency.

The results show that the performances of the new device and the predicate device are similar and do not raise any new questions concerning the safety and effectiveness of the new device.

Clinical Testing:
No clinical testing was required to support this submission.

Conclusions drawn from conducted performance tests:
Results of performance testing demonstrate that the functionality, integrity, and safety and effectiveness of the new devices, Implantmed Plus II and the Piezomed Plus II Module, are assured for their intended use. The test results confirm that no new issues concerning the safety or effectiveness have arisen. In conclusion, this demonstrates that the subject device is substantially equivalent to the predicate devices.