July 3, 2025

W&H Dentalwerk Buermoos GmbH
Gerhard Weidler
Regulatory Affairs Manager
Ignaz-Glaser-Strasse 53
Buermoos, Salzburg 5111
Austria

Re: K243280
Trade/Device Name: Piezomed Pro (Piezomed Pro module M-PM100 incl. handpiece M-PH350, Piezomed Pro instruments (various tips) and accessories)
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, And Throat Electric Or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL, DZI, JDX, HWE
Dated: October 17, 2024
Received: June 5, 2025

Dear Gerhard Weidler:

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243280

Device Name

Piezomed Pro (Piezomed Pro module M-PM100 incl. handpiece M-PH350, Piezomed Pro instruments (various tips) and accessories)

Indications for Use *(Describe)*

The piezoelectric surgical system is indicated for: osteotomies, osteoplasties, drilling and shaping of hard tissue. Including:
- Otolaryngology,
- Maxillofacial surgery,
- hand- & foot-surgery and
- plastic & reconstructive 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 K243280

DATE PREPARED	03.07.2025
APPLICANT	W&H Dentalwerk Bürmoos GmbH Ignaz-Glaser-Strasse 53 5111 Bürmoos Austria 0043 - 6274/6236-0
CONTACT PERSON	Mag. Dr. Gerhard Weidler Regulatory Affairs Manager 0043 - 6274/6236-102 gerhard.weidler@wh.com; ra@wh.com

1 Device Name:

Trade Name:	Piezomed Pro
Common Name:	Piezomed Pro module M-PM100, incl. Piezomed Pro handpiece M-PH350 and Piezomed Pro Instruments (various tips).

2 Classification / Primary Product Code:

The Piezomed Pro can be classified according to following device name and product code:

Primary Product Code	Device	Regulation Description	Regulation Medical Specialty	Review Panel	Regulation Number	Device Classification
ERL	Drill, Surgical, Ent (Electric or Pneumatic) Including Handpiece	Ear, nose, and throat electric or pneumatic surgical drill.	Ear Nose & Throat	Ear Nose & Throat	874.4250	2

3 Predicate Device / Reference Device:

Device	Predicate Device	Reference Device	510(k) Number	510(k) Holder
Piezosurgery® Plus	**X**		K153743	Mectron S.p.a.
Piezotome® M+		**X**	K163610	SATELEC

4 Device Description:

The new device, the “Piezomed Pro”, is an ultrasonic surgical modular system which has to be connected to W&H’s AMADEO device (K213221). The new device is an ultrasonic surgical system whose basic function is the conversion of electrical energy into mechanical vibration.
In addition, a physiological saline solution is pumped to the treatment site with a displacement pump, depending on the treatment.
Using a control unit with electronics, the user can change several operating parameters within predefined limits:

- oscillation amplitude, 5 to 100% in steps of 5 (100 % corresponds to max. power)
- coolant flow rate via pump speed control; 5 to 100% in steps of 5 (100% corresponds to max. water quantity)

The device is activated or deactivated via a foot control.

5 Intended Use/Indications for Use:

The piezoelectric surgical system is indicated for: osteotomies, osteoplasties, drilling and shaping of hard tissue. Including:

- Otolaryngology,
- Maxillofacial surgery,
- hand- & foot-surgery and
- plastic & reconstructive surgery.

6 Technological Characteristics

6.1 Device Characteristics Table

	New Device	Predicate Device	Reference Device	Result
Device Name	Piezomed Pro	Piezosurgery® Plus	Piezotome® M+	---
Regulation Number	874.4250	888.4580	888.4580	**Note 1)**
Class	2	2	2	identical
Primary Product Code	ERL	JDX	JDX	**Note 1)**

	New Device	Predicate Device	Reference Device	Result
Secondary Product Codes	DZI, JDX, HWE	DZI, ERL, HBE, HWE	HWE, DZI, ERL, HBE	**Note 1)**
Indications for use	The piezoelectric surgical system is indicated for: osteotomies, osteoplasties, drilling and shaping of hard tissue. Including: - Otolaryngology, - Maxillofacial surgery, - hand- & foot-surgery and - plastic & reconstructive surgery.	The Piezosurgery® Plus is an ultrasonic surgical system consisting of handpieces and associated tips for osteotomy, osteoplasty and drilling in a variety of surgical procedures, including but not limited to: - Otolaryngology - Oral/maxillofacial - Hand and foot - Neurosurgery - Spine - Plastic/reconstructive, and - Orthopedic surgery. The device may also be used with endoscopic visual assistance to perform the above listed procedures.	Piezotome® M+ is an ultrasonic surgical system consisting of handpieces and associated tips, for cutting bone, bone substitutes and metal. The system can be used for osteotomy, osteoplasty, decorticating, drilling, shaping, and smoothing of bones and teeth, in a variety of surgical procedures, including: - general orthopedic, - otolaryngological, - maxillofacial, oral, - hand, foot, - neurosurgical spine, and - plastic/reconstructive surgery. Piezotome® M+ is to supply utilities to and serve as a base for dental tools such as ultrasonic scaler, bone cutting instrument and accessories for use by qualified dental practitioners in periodontics, endodontics, scaling, prosthesis and oral surgery.	identical
Operating principle	The basic function is the conversion of electrical energy into mechanical vibration. In addition, a physiological saline solution is pumped to the treatment site with a displacement pump, depending on the treatment. Using a control unit with electronics, the user can change several operating parameters within predefined limits: - oscillation amplitude, 5 to 100% in steps of 5 (100 % corresponds to max. power) - coolant flow rate via pump speed control; 5 to 100% in steps of 5 (100% corresponds to max. water quantity) The scaler is activated or deactivated via a foot control.	The Piezosurgery Plus device is a surgical system that uses ultrasonic energy to generate mechanical micro-vibration of associated inserts, to perform cutting of bony structures in the procedures defined by its intended use. The Piezosurgery Plus system consists of a control unit which provides control and power functions, two different detachable surgical handpieces which provide the ultrasonic mechanical energy, two peristaltic irrigation pumps, two irrigation tubing systems, a range of single use insert tips, torque wrenches, and a foot-pedal.	An electrical signal emitted by the medical device is supplied to the dental piezo-ultrasonic handpiece. It comprises a piezoelectric ceramic transducer, which converts the electrical signal into ultrasonic vibrations. Mechanical vibrations are transmitted to a tip attached to the end of the ultrasonic handpiece. The vibrations, applied with a very gentle pressure, cut the bone with ultrasounds. They act distinctively on the bone, minimizing the risks of damaging the soft tissue, thereby guaranteeing a more precise and safe procedure with less strain on the surgeon's hand. This ultrasonic piezoelectric surgical procedure also improves bone healing.	identical

	New Device	Predicate Device	Reference Device	Result
Technological characteristics (mechanisms of action)	The basic function is the conversion of electrical energy into mechanical vibration of tips.	Piezoelectric ultrasonic technology that generates mechanical micro-vibration of the insert tips.	The Ultrasonic Handpieces are equipped with a Piezoelectric Transducer. The Piezoelectric transducer converts the Electrical Signal delivered by the Console into mechanical micro-vibrations.	identical
Frequency	50-60 Hz	50-60 Hz	50-60 Hz	identical
Operating frequency	22-35 kHz	24-36 kHz	28 kHz	similar
Operating mode	Intermittent operation	Intermittent operation	Intermittent operation	identical
Electric classification	Class I, Type B	Class I, Type B	Class I, Type BF	identical to predicate
Components	> Piezomed Pro M-PM100 > Power cord > Piezomed Pro handpiece M-PH350 > Various tips > Tip changer M-CI350 > Irrigation tubing	The Piezosurgery Plus system consists of a > control unit which provides control and power functions, > two different detachable surgical handpieces which provide the ultrasonic mechanical energy, > two peristaltic irrigation pumps, > two irrigation tubing systems, > a range of single use insert tips, torque wrenches, and > a foot-pedal.	PIEZOTOME M+ consists of > a console, > a multifunction footswitch, > two reusable handpieces, > a range of dental tips, a range of bone surgery tips, > two Irrigation pumps with > irrigation tubings and flat wrenches for tips.	identical **Note 2)**

Note 1) The predicate shares the same intended use and functions, however the JDX primary product code is now exempt. Therefore, ERL was chosen as the primary product code for the subject device because it corresponds with the highest regulatory class and has the most relevant technology to be used for comparison. Neurological applications are not part of this submission.

Note 2) The foot control and control unit, including the peristaltic pump, are part of the AMADEO System (K213221).

6.2 Summary of Technological Characteristics

The proposed devices are similar in terms of basic function, operating principles and intended use and have similar technological characteristics. The basic materials used on the Piezomed Pro are also used in the legally marketed predicate/reference devices.

7 Performance Data:

Non-clinical testing has been performed to show that the device performs as intended and is substantially equivalent to the predicate device (K153743).

7.1 Biocompatibility

A chemical and biological evaluation of biocompatibility according to ISO 10993-1 was carried out and all tests were successfully completed.
Tests were performed according to ISO 10993-5 for cytotoxicity, to ISO 10993-10 for skin sensitization, to ISO 10993-23 for irritation as well as ISO 10993-12 and ISO 10993-18 for chemical characterization.

7.2 Electromagnetic Compatibility and Electrical Safety

Electrical safety and EMC testing were conducted. The Piezomed Pro is in compliance with IEC 60601-1 and IEC 60601-1-2.

7.3 Re-processing Validation

Reprocessing validation was provided per the FDA Guidance Document for “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”. Cleaning and intermediate level disinfection validation was provided for the control unit. Cleaning and sterilization validation was provided for the instruments and handpiece.

7.4 Performance Testing

Performance and functional testing (life-time and service-time tests for device components, falling and vibration tests acc. to ISO 18398 as well as tests for the resistance of basic materials to disinfectants acc. to ISO 21530) of the Piezomed Pro to test the application, settings, and features per the device specifications requirements was performed.

8 Software and Cybersecurity:

A risk-based software and cyber-security verification/evaluation according to IEC 62304 and the FDA Guidance Documents “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” was conducted and the necessary software documentation was provided.

9 Substantial Equivalence Summary / Conclusion:

Based on available 510(k) information provided herein, the Piezomed Pro module M-PM100, incl. handpiece M-PH350 and accessories, is considered substantially equivalent to the predicate device in terms of indications for use, technology and performance specifications.
There are no differences between the devices which may raise new issues concerning safety or effectiveness.