July 14, 2023

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

Re: K223173
Trade/Device Name: Proxeo ULTRA (PB-510, PB-520 and PB-530)
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: June 21, 2023
Received: June 23, 2023

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 (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)*
K223173

Device Name
Proxeo ULTRA (PB-510, PB-520 and PB-530)

Indications for Use *(Describe)*
Drive unit with a piezoceramic oscillating system, which moves the tip in a linear oscillation.
The drive unit is used for the removal of supragingival calculus and subgingival concretions and for endodontic application and preparation of tooth enamel.

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 K223173

DATE PREPARED	July 13, 2023
APPLICANT	W&H Dentalwerk Buermoos GmbH Ignaz-Glaser-Straße 53 5111 Bürmoos Austria 0043 - 6274/6236-0 0043 - 6274/6236-55
CONTACT PERSON	Mag. Dr. Gerhard Weidler Regulatory Affairs Manager 0043 - 6274/6236-9339 gerhard.weidler@wh.com

1 Device Name:

Trade Name:	Proxeo ULTRA (PB-510, PB-520 and PB-530)
Common Name:	Proxeo ULTRA
Device Classification Name:	Ultrasonic scaler

2 Classification / Product Code:

The Proxeo ULTRA can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Scaler, Ultrasonic	Ultrasonic scaler	Dental	Dental	ELC	872.4850	2

3 Predicate Device / Reference Device:

Device	Predicate Device	Reference Device	510(k) Number	510(k) Holder
Scaler, Ultrasonic	Multipiezo Pro	----------	K140965	Mectron Spa
	----------	Piezon 250	K132445	E.M.S. ELECTRO MEDICAL SYSTEMS S.A.

4 Device Description:

The Proxeo ULTRA is a drive unit including handpieces with a piezoceramic oscillating system, which moves the tip in a linear oscillation.

The drive unit is used for the removal of supragingival calculus and subgingival concretions and for endodontic application and preparation of tooth enamel.

The medical device consists of the following components that are also included in the scope of delivery:

- Control unit (PB-510, PB-520, and PB-530)
- Handpiece (PB-5 L, PB-5 L S, and PB-5 L Q)
- Foot control (wired, wireless)
- Power supply, instruction for use and other accessories

The scaler tips are moved with a piezo-scaler handpiece by converting electrical energy into mechanical vibration. The coolant (water) is directed to the treatment site via a solenoid valve and a control unit via the tip. The scaler tips are re-usable [diamond-coated tips are single use only] and delivered non-sterile. Tips for use with Piezo Scaler for the following dental applications:

- Scaling-tips
- Periodontic-tips
- Implant-cleaning-tips
- Endodontic-tips
- Tips for restoration and prosthetics

With the foot control, corresponding device functions can be operated with the foot. These functions include, for example, program selection (button), operation of coolant function (button), motor direction of rotation selection (button), motor speed level (variable with pedal), power piezo handpiece (variable with pedal).

Bluetooth Low Energy technology is used in the wireless foot controls (C-NW) to make this possible wirelessly as well. The foot controls are powered internally by a rechargeable battery (C-NW) or an external power source (C-NF).

5 Indications for Use

Drive unit with a piezoceramic oscillating system, which moves the tip in a linear oscillation.

The drive unit is used for the removal of supragingival calculus and subgingival concretions and for endodontics application and preparation of tooth enamel.

6 Technological Characteristics

The technological characteristics of Proxeo Ultra are the same as the technological characteristics of the predicate device.

6.1 Device Characteristics Table

	W&H Dentalwerk Bürmoos GmbH – Proxeo Ultra (New Device)	**Mectron Spa– Multipiezo Pro (Predicate Device)**	**EMS Electro Medical Systems SA – Piezon 250 (Reference Device)**	**Result**
Device Name	Proxeo Ultra	Multipiezo Pro	Piezon 250	---
Regulation Number	872.4850	872.4850	872.4850	**Identical**
Class	II	II	II	**Identical**
Product Code	ELC	ELC	ELC	**Identical**
Regulation Generic Name	Ultrasonic scaler	Ultrasonic scaler	Ultrasonic scaler	**Identical**
Indications for Use	Drive unit with a piezoceramic oscillating system, which moves the tip in a linear oscillation. The drive unit is used for the removal of supragingival calculus and subgingival concretions and for endodontic application and preparation of tooth enamel.	The Multipiezo Pro and Multipiezo are piezoelectric ultrasonic dental scalers intended for use, with the appropriate associated tip inserts, in the following dental applications: > Scaling: All general procedures for removal of supragingival/subgingival and interdental calculus/ plaque deposits	The Piezon 250 is a device for delivering ultrasonic movement and irrigant to a stainless-steel tip which is used by a dentist or dental hygienist. The indications for use are: > Periodontal pocket lavage with simultaneous ultrasonic tip movement	**Equivalent**

	W&H Dentalwerk Bürmoos GmbH – Proxeo Ultra (New Device)	Mectron Spa– Multipiezo Pro (Predicate Device)	EMS Electro Medical Systems SA – Piezon 250 (Reference Device)	Result
		> Periodontology: Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning > Endodontics: All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation Restorative and Prosthetics: All general restorative procedures including cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations, inlay/onlay condensation, implants/restorations cleaning.	> Scaling and root planning Removal of supra and subgingival calculus and stains from teeth	
Functions	The basic function is the conversion of electrical energy into mechanical energy (linear oscillation).	The Multipiezo Pro device is dental piezoelectric ultrasonic device that use ultrasonic energy to generate mechanical micro-vibration of the inserts to perform the dental procedures defined in their intended use.	Ultrasonic scaling	**Identical**
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	**Identical**

	W&H Dentalwerk Bürmoos GmbH – Proxeo Ultra (New Device)	Mectron Spa– Multipiezo Pro (Predicate Device)	EMS Electro Medical Systems SA – Piezon 250 (Reference Device)	Result
Electric power supply	100-230 V ± 10% 50-60 Hz	100-240 VAC 50-60 Hz	100-240 VAC 50-60 Hz	**Equivalent**
Operating Mode	Continuous Operation	Continuous Operation	Continuous Operation	**Identical**
Electric classification	B	B	BF	**Equivalent**
Ultrasonic frequency	22-35 kHz	24-36 kHz	24-32 kHz	**Equivalent**
Foot control	> wireless > wired	> wired	> wired	**Equivalent**
Components	> Control Unit > Handpiece (in different versions) > Foot control (in different versions) > Power supply, instruction for use > Scaler tips	> Control Unit > Handpiece > Foot control > Power supply > Scaler tips	> Control Unit > Handpiece > Foot control > Instruments > Irrigating liquid bottle	**Equivalent**

6.2 Summary of Technological Characteristics

The proposed devices are similar in terms of design, operating principles and intended use and have similar technological characteristics as the predicate devices. The materials used on these devices are also used in the legally marketed predicate devices.

7 Performance Data:

Non-clinical testing has been performed showing that the device performs as intended and are substantially equivalent to the predicate device (K140965) and the reference device (K132445).

7.1 Biocompatibility

An evaluation of biocompatibility according to ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-17, ISO 10993-18 and ISO 10993-23 was performed.

7.2 Electromagnetic Compatibility and Electrical Safety

Electrical safety and EMC testing were conducted. The Proxeo ULTRA is in compliance with IEC 60601-1, IEC 80601-2-60 as well as 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 and foot controller. Cleaning and sterilization validation was provided for the scaler tips and handpieces.

7.4 Bench Testing

Functional testing of the Proxeo ULTRA to test the application, settings, and features per the device specifications requirements.

8 Software:

Software verification according to IEC 62304 and the FDA Guidance Document for Software Contained in Medical Device was conducted and the necessary software documentation according to the defined moderate level of concern was provided.

9 Substantial Equivalence Summary / Conclusion:

Based on available 510(k) information provided herein, our Proxeo ULTRA is considered to be substantially equivalent to the predicate device Multipiezo Pro and the reference device Piezon 250 in terms of indication for use, materials and technology, design and performance specifications.