W&H Dentalwerk Buermoos GmbH
Anja Lindner
Regulatory Affairs Specialist
Ignaz-Glaser-Straße 53
Burmoos, Salzburg 5111
AUSTRIA

March 26, 2019

Re: K181858
Trade/Device Name: Electric Handpiece Motor EM-12 L
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EBW
Dated: December 21, 2018
Received: December 26, 2018

Dear Anja Lindner:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.03.26 11:19:33 -04'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181858

Device Name
Electric Handpiece Motor EM-12 L

Indications for Use *(Describe)*
Electric Handpiece Motor EM-12 L is a brushless DC electric micromotor controlled by a control unit.
The electrical drive, EM-12 L is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as 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.

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
K181858

Submitter	W & H DENTALWERK BÜRMOOS GMBH Ignaz-Glaser-Strasse 53 A - 5111 Bürmoos Austria Tel.: 0043 -6274 / 6236 -397 Fax: 0043 -6274 / 6236 -55
Registration Number	9681479
Contact Person	Mag. Anja LINDNER
Date of Preparation	March 25, 2019
Device Name	Electric Handpiece Motor EM-12L
Classification Name	Dental Handpiece and Accessories
Regulation Number	21 CFR 872.4200
Regulatory class	I
Product Code	EBW
Predicate Devices	Predicate device for the electric motor EM-12 L: “Electric Handpiece Motor”, A-dec/W&H cleared under K133776
Device Description	The W&H electric motor EM-12 L is designed to accommodate existing and new handpiece attachments (already cleared for market under K070663 and K162926) for the purpose of performing dental procedures as described above. The advantage to driving a handpiece with this electro motor is the adjustable speed and near-constant torque applied by the electric brushless micro motor. The system will be used in an integrated configuration on the dental operatory chair system. The motor controller is contained within the control head (Dental unit) and acquires +24 VAC from the chair system 300 W power supply secondary voltage output. The motor tubing extends from the motor controller inside the control head to the micro-motor with ISO-E-coupler suitable to a handpiece attachment for the intended dental procedure. The Electric Handpiece Motor is to be installed in A-dec dental operative units. The power/CAN-Bus will be provided by the dental unit controller board and connected to the controller.

<table>
<tr><td></td><td>The dental unit controller board, display, foot control and active handpiece switch are part of the system manufacturer dental unit and not a W&H part.

The motor will be directly connected to the motor controller by the system manufacturer (not W&H).

The system manufacturer gets an installation manual for the motor controller and the motor.</td></tr>
<tr><td>Indications for Use:</td><td>Electric Handpiece Motor EM-12 L is a brushless DC electric micromotor controlled by a control unit.
The electrical drive, EM-12 L is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.</td></tr>
<tr><td>Technological Characteristics</td><td>
<table>
<tr><th>Item</th><th>New device EM-12 L</th><th>Predicate device EA-53</th><th>Judgment</th></tr>
<tr><td>Power supply</td><td>100 – 240 V AC</td><td>100 – 240 V AC</td><td>Same</td></tr>
<tr><td>Speed range</td><td>100 to 40,000 rpm</td><td>100 to 40,000 rpm</td><td>Same</td></tr>
<tr><td>Supply connection</td><td>ISO 9168</td><td>ISO 9168</td><td>Same</td></tr>
<tr><td>Air pressure</td><td>3 ± 0.3 bar</td><td>3 ± 0.3 bar</td><td>Same</td></tr>
<tr><td>Water pressure</td><td>0.5 to 3 bar</td><td>0.5 to 3 bar</td><td>Same</td></tr>
<tr><td>Chip Air pressure</td><td>0.5 to 3 bar</td><td>0.5 to 3 bar</td><td>Same</td></tr>
<tr><td>Motor torque</td><td>3 Ncm</td><td>3 Ncm</td><td>Same</td></tr>
<tr><td>Light</td><td>yes</td><td>yes</td><td>Same</td></tr>
</table>
The technical principle is the same as within the predicate device.

The main differences between the subject and the predicate device are the different labeling especially the name designation and the reciproc®/wave one® function, which do not raise any additional question regarding substantial equivalence as the predicate device already has a kind of</td></tr>
</table>

reciprocating movement

The Electric Handpiece Motor is to be installed in A-dec dental operative units.

Comparison of the device to the predicate device

Item	New device	Predicate device	Judg-ment
Name	W&H Electric Motor EM-12L	A-Dec Electric Motor EA-53	- - -
Photo			- - -
Where used	Dental practice, dental clinic.	Dental practice, dental clinic.	same
Manu-facturer	W&H Dentalwerk Bürmoos GmbH www.wh.com	A-dec	- - -
510(k)	Submitted K181858	K133776 submitted A-dec, Inc.	- - -
Indication for Use	Electric Handpiece Motor EM-12 L is a device system comprised of a control unit that drives a DC electric micromotor. The electrical drive, EM-12L is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.	The A-dec/W&H Electric Motor Kit is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment with use of a straight, right-angle, or contra-angle ISO E-type handpiece attachment of equal speed, gear-reduction speed, or gear-increasing speed.	Similar

	New Device MC-1.0 / MC-2.0 E	Predicate Device CM-1.1 / CM-2.1	Judgement
Enclosure	Maximum Size	Maximum Size	Same
Length	142 mm	138 mm	Similar
Width	60 mm	60 mm	Same
Height	43 mm	43 mm	Same
Material	Flame-rated plastic	same	Same
Installation	By qualified and authorized personnel	same	Same
Digital Interface			
Protocol	CAN	CAN	Same

The only difference in the subject device and the predicate device is minor dimensional changes and addition of a reciprocating feature.

The target field of application, the intended use, functions and technological features, performance parameter and

	material are the same or, at least, quite similar to those of the predicate device.
Non-clinical testing	Electrical Safety Tests according to IEC 60601-1:2005+A1:2012 (3.1 Edition), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Electromagnetic Compatibility Test according to IEC 60601-1-1:2007: General requirement for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests Product testing of the Electric Handpiece Motor's function and life cycle testing were performed according to ISO 14457:2012: Dentistry – Handpieces and Motors. Motor cooling air, spray air supply and water supply was tested according to ISO 14457:2012 Various temperature testing was also performed according to ISO 14457:2012 Reprocessing validation per the FDA Guidance for Reprocessing of Medical Devices in Health Care Setting issued on March 17, 2015 Software Documentation of Moderate Level of Concern per the FDA Guidance Document for Software Contained in Medical Devices issued on May 11, 2005 Software validation according to IEC 62304:2006: Medical device software – Part 1: Guidance on the application of ISO 14972 to medical device software Thermal safety according to the standard IEC 62471:2006: Photobiological safety of lamps and lamp systems Evaluation of biocompatibility is based on ISO 10993. The evaluation meets the requirements.

Clinical Testing	Clinical performance testing was not conducted.
Conclusion	W&H considers the Electric Handpiece Motor EM-12 L to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in intended use, principles of operation, functional design, and establishment medical use. Differences between the devices shown in the comparison section above are minor and do not have any negative effect on equivalence.