May 26, 2022

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

Re: K213221
Trade/Device Name: AMADEO, M-UK1015 (incl. attachments 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
Dated: April 21, 2022
Received: April 27, 2022

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 (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, 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)*
K213221

Device Name
AMADEO (M-UK1015, incl. attachments and accessories)

Indications for Use *(Describe)*
The drive unit for surgical transmission instruments is indicated for: drilling, milling, cutting, sawing, screwing (for positioning) of osteosynthesis screws, implants and plate systems in soft and hard tissue.

Including: ENT surgery and Maxillofacial 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.

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510(k) Summary K213221

DATE OF APPLICATION	May 25, 2022
APPLICANT	W&H Dentalwerk Bürmoos 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:	AMADEO (M-UK1015 incl. attachments and accessories)
Common Name:	AMADEO
Device Classification Name:	Ear, nose, and throat electric or pneumatic surgical drill

2 Classification / Product Code

The AMADEO can be classified according to following device names and product codes:

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

Secondary Product Code	Device	Regulation Description	Regulation Medical Specialty	Review Panel	Regulation Number	Device Classification
DZI	Drill, Bone, Powered	Bone cutting instrument and accessories.	Dental	Dental	872.4120	2

3 Predicate Device / Reference Device

Device	Predicate Device	Reference Device	510(k) Number	510(k) Holder
AMADEO	Primado2	----------	K132264	NSK
	----------	Implantmed	K161957	W&H Dentalwerk

4 Device Description

The AMADEO is an electrical drive unit, including motor, attachments and accessories, for surgical transmission attachments which is indicated for: drilling, milling, cutting, sawing, screwing (for placement) of osteosynthesis screws, implants and plates, in soft and hard tissue.

The foreseen areas of application will be:

- ENT (ear, nose, throat) surgery
- Maxillofacial surgery

The basic function is the conversion of electrical energy into a mechanical rotary motion. The control unit is used to control the connected motor and the integrated pump. Depending on the treatment, a physiological saline solution is pumped to the treatment site by a displacement pump. A single-use sterile disposable irrigation tubing set is supplied within the scope of delivery and offered as an accessory.

The integrated touch display is used to monitor the actual settings and to change, within predetermined limits, the operating parameters.

The foot control is used for activation/deactivation of the motor and for changing parameters e.g. program, pump state and motor direction.

5 Indications for Use

The drive unit for surgical transmission instruments is indicated for: drilling, milling, cutting, sawing, screwing (for positioning) of osteosynthesis screws, implants and plate systems in soft and hard tissue.

Including: ENT surgery and Maxillofacial surgery

6 Technological Characteristics

The technological characteristics of the AMADEO are equivalent to the technological characteristics of the predicate device.

6.1 Device Characteristics Table

	W&H Dentalwerk Bürmoos GmbH – AMADEO (New Device)	**NSK – Primado2 (Predicate Device)**	**Result**
Device Name	AMADEO	Primado2	**-----**
Indications for Use	The drive unit for surgical transmission instruments is indicated for: drilling, milling, cutting, sawing; screwing (for positioning) of osteosynthesis screws, implants and plate systems in soft and hard tissue. Including: ENT surgery and Maxillofacial surgery	The Primado2 is an electrically powered total surgical system which is intended for cutting, drilling, sawing and otherwise manipulating soft tissue, hard tissue, bone, bone cement, prosthesis, implant and other bone related tissue in a variety of surgical procedures, including but not limited to Cranial (craniofacial and maxillofacial), ENT, Endoscopic/Arthroscopic, Neuro, Orthopedic, Spinal, and General surgical procedures.	**Equivalent** [1)]
Regulation Number	874.4850	874.4850	**Identical**[1)]
Secondary Regulation Number	872.4120	872.4120	**Identical** [1)]
Class	II	II	**Identical**
Product Code	ERL, DZI	ERL, DZI, GEY, HWE, HBC, DZJ, HBE, GFF, EQJ	**Equivalent**[1)]
Regulation Generic Name (Primary Code, Neurology excluded)	Drill, Surgical, Ent (Electric or Pneumatic) Including Handpiece	Drill, Surgical, Ent (Electric or Pneumatic) Including Handpiece	**Identical**[1)]
Sterility	Provided non-sterile	Provided non-sterile	**Equivalent**
Use	Rx only	Rx only	**Equivalent**

Basic functions	The basic function 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 control unit with electronics, the user can change the most crucial operating parameters within predetermined limits: > Motor speed > Torque setting > Coolant flow rate via pump speed control 0 to 100% (100% corresponds to max. amount of water) > Transmission ratio with various handpieces and contra angle handpieces)	The Primado2 consists of the control unit, the motor, the foot control and various handpieces for use with specific motors. The control unit drives the motors during procedures and is used to control the functions related to that motor such as speed and rotational direction. The control unit also incorporates the irrigation pump and controls the irrigation functions. The software allows for the control of the devices features such as: > speed control > rotational direction > irrigation control etc.	**Equivalent**
Mains voltage Frequency	120 V 50-60 Hz	120 V 50/60 Hz	**Identical**
Operating Mode	intermittent duty S3 (load time max. 3min / rest time min. 5min)	intermittent duty (load/rest depending on motors used)	**Equivalent**
Foot control	> wireless > wired	> wired	**Equivalent**
Components	> Control Unit > Motor > Handpiece (in different versions) > Foot control (in different versions) > Power cord > Instruction for use	> Control Unit > Motor (in different versions) > Handpiece (in different versions) > Foot control > Power cord > Instruction for use	**Equivalent**

[1)] The indications of use of the AMADEO do not include neurological indications. Considering FDA's Guideline "Bundling Multiple Devices or Multiple Indications in a Single Submission, issued June 22, 2007" bundling of different review panels within different review division/group, OHT1 for ENT, Dental and OHT5 for Neurology, is not appropriate. The removal of neurological indications does not influence the device's substantial equivalence. Burs or other corresponding accessories are not part of the submission.

6.2 Summary of Technological Characteristics

The proposed device is similar in terms of design, operating principles and intended use and has similar technological characteristics as the predicate device. The new device shares technological characteristics with the predicate device but also has some differences. The differences in the technological characteristics can be evaluated as minor and reflect market strategy and/or perceived user preferences. The differences do not impact substantial equivalence of the device.

The materials used on this device are also used in the legally marketed predicate device.

7 Performance Data

Non-clinical testing has been performed showing that the device performs as intended and are substantially equivalent to the predicate device Primado2 (K132264).

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 AMADEO is in compliance with IEC 60601- 1 as well as IEC 60601-1-2.

7.3 Reprocessing 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 motor cable and handpieces.

7.4 Bench Testing

Functional testing of the AMADEO to test the application, settings, features, and touchscreen 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 AMADEO is considered to be substantially equivalent to the predicate device Primado2 in terms of indication for use, materials and technology, design and performance specifications.