W & H Dentalwerk Buermoos GmbH
Mag. Anja Lindner
Manager Regulatory Affairs
Ignaz-Glaser-StraBe 53
5111 Buermoos
AUSTRIA

December 8, 2017

Re: K171553
Trade/Device Name: W&H Assistina Twin
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: November 7, 2017
Received: November 9, 2017

Dear Mag. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171553

Device Name
Assistina Twin MB-302

Indications for Use *(Describe)*
Unit for cleaning the spray channels and lubricating the moving parts of dental and surgical handpieces, turbines, air motors and air-driven dental scalers.

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

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 Submission	7th of November, 2017
Device Name	Assistina TWIN MB-302
Classification Name	Dental Handpieces and Accessories
510(k) number	K171553
Regulation Number	21 CFR 872.4200
Regulatory class	I
Product Code	EFB
Predicate Devices	Primary Predicate: “Care3 Plus”, NSK.; cleared under K081811 Reference Predicate: Assistina 301+, W&H Dentalwerk Bürmoos, cleared under K010127. The predicate has not been subject to a design-related recall.
Device Description	The W&H **Assistina TWIN MB-302** is an electrically and pneumatically driven maintenance device with the following functions: - Rinsing the spray channels with cleaning solution (water basis) and drying with compressed air. - Lubricating the rotational internal gear parts. The oil is spread and a constant lubrication film is set up.

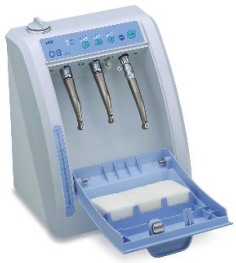
Technical data:

Assistina TWIN MB-302	
Cycle duration	10 sec.
Air consumption	Approx. 40 Nl/min.
Operating pressure	5 – 10 bar (controlled via an integrated, automatic pressure controller)
Supply voltage	100 – 240 VAC
Max. power consumption	18 VA
Weight	3,8 kg
Dimensions	297 x 435 x 190 mm

Indications for Use:

Unit for cleaning the spray channels and lubricating the moving parts of dental and surgical handpieces, turbines, air motors and air-driven dental scalers.

Technological Characteristics

Item	New device	Predicate device	Judgment
Name	W&H Assistina TWIN MB-302	NSK Care3 Plus	- - -
Photo			- - -
Where used	Dental practice, dental clinic.	Dental practice, dental clinic.	same
Manufacturer	W&H Dentalwerk Bürmoos GmbH www.wh.com	Nakanishi Inc. www.nsk-inc.com	- - -
510(k)	------	K081811	- - -

Indication for Use	Unit for cleaning the spray channels and lubricating the moving parts of dental and surgical handpieces, turbines, air motors and air- driven scalers.	Care3 Plus is intended for internal cleaning e.g. purging of old lubricant, for the maintenance of rotating dental and surgical instruments.	Similar
Scope of submission	- Assistina TWIN MB-302 device - Adapter HPI - Air supply hose - TWIN Care Set (including lubricant, detergent and HEPA filter) - Power supply unit	- Care3 unit - AC power cord - Maintenance oil - Oil supply funnel with filter - Mist filter set - Air tube - Oil absorber sheet - O- ring set - Test bur - Magnet	Similar
Dimensions	297 x 435 x 190mm (WxDxH)	280 x 275 x 360mm (WxDxH)	Similar

Technical Data:

Item	**New device MB-302**	**Predicate device Care3 Plus**	**Judgment**
Power supply	100 – 240 V AC ± 10%	120 – 230 V AC ± 10%	Similar
Power consumption	18 VA	19.5 VA	Similar
Air pressure	5 – 10 bar	3.5 – 6 bar	Similar*
Cleaning	Clean the process chambers with a dry cloth and wipe- disinfect the exterior and the process chambers.	*Not known*	Similar

Process liquids:

Lubricant	W&H Service Oil F1 MD-302 (cartridge containing 200ml lubricant)*	NSK maintenance oil (1 liter bottle)	Similar
Detergent	W&H Activefluid MC-302 (cartridge containing 200ml detergent)**	not applicable	- - -

**Service oil is the same as already cleared for market with Assistina 301+ (K010127) only the packaging looks a little different
***Activfluid is quite the same as the Activefluid cleared for market with Assistina

	301+ only without alcohol and is therefore no dangerous good any more. The technical principle is the same as within the predicate device. The main technological characteristics are the same or, at least, quite similar to those of the comparable product. The intended use is identical to the predicate device
Comparison of the device to the predicate device	The target field of application, the intended use, performance parameter and material are the same or, at least, quite similar to those of the predicate device. The only differences are some technological features: different modes, different number of buttons, different number of chambers. The predicate device has no cleaning function. However, these differences do not have any negative effect on the safety and/or effectiveness of the subject device. The new device is substantially equivalent to the predicate device.
Performance Testing	Electrical Safety Tests according to IEC 61010-1, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements for safety Electromagnetic Compatibility Test according to IEC 61326-1: Electrical equipment for measurement, control and laboratory use, EMC requirements – Part 1: General requirements for safety Software validation according to IEC 62304:2006: Medical device software – Part 1: Guidance on the application of ISO 14972 to medical device software Biological Assessment and Cytotoxicity Testing of the liquids according to EN ISO 10993 was performed. The evaluation meets the requirements. Risk Analysis according to ISO 14971. Testing of cleaning performance according to ISO 15883. Validation of wipe disinfection according to the IFU. Different Bench Tests like Lifetime tests – Activation of start button, moving/removing of sliding door, Lifecycle test according to internal requirements. The results demonstrate substantial equivalence in this regards.
Clinical Testing	Clinical data were not needed for this new product.
Conclusion	W&H considers the Assistina Twin MB-302 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 side-by-side comparison table above are minor and do not have any negative effect on equivalence.