DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 9, 2015

Kaltenbach & Voigt Gmbh
Mr. Stefan Trampler
Director, Regulatory Affairs
Bismarckring 39
Biberach, 88400
GERMANY

Re: K143465
Trade/Device Name: MASTERmatic LUX
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EFA
Dated: March 9, 2015
Received: March 13, 2015

Dear Mr. Trampler:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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 RA Statement below.

510(k) Number **K143465**

Device Name
MASTERmatic LUX

Indications for Use (Describe)

The MASTERmatic LUX handpieces are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration Office
of Chief Information Officer Paperwork
Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

KaVo. Dental Excellence.

Section V - 510(k) Summary

Submitter:

Kaltenbach & Voigt GmbH
Bismarckring 39
88400 Biberach
Stefan Trampler - Contact Person
49 (7351) 56 3515 - Phone number
+49 (7351) 56 7 3515 - Facsimile

Date Summary Prepared: March 09, 2015

Device Name:

- Trade Name - MASTERmatic LUX
- Common Name - Handpiece, contra- and right-angle attachment, dental
- Classification Name - Dental handpiece and accessories, per 21 CFR § 872.4200
- Device Class - Class I
- Product Code - EGS

Devices for Which Substantial Equivalence is Claimed:

- A-dec 1 W&H Synea Air-Driven Highspeed Handpieces, Models TA-98, TA-97 1 A-dec 1 W&H Synea Handpiece Attachment, Models WA-99LT, WA-86LT, WA-66LT, WA-56LT, HA-43LT (K070663) marketed by W & H DENTALWERK BUERMOOS GMBH.

Device Description:

The MASTERmatic LUX electrical-driven handpieces

- MASTERmatic LUX M25 L
- MASTERmatic LUX M20 L
- MASTERmatic LUX M10 L
- MASTERmatic LUX M07 L
- MASTERmatic LUX M29 L
- MASTERmatic LUX M05 L

are dental handpieces for the use by a trained professional in the field of general dentistry. The devices are electrical-powered handpieces that are reusable and ergonomically shaped, and provided with a fiber optic light system. The devices can be sterilized by the steam autoclave method. Through the tube and the electrical motor connected to a dental unit, the MASTERmatic LUX handpieces equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receive the energy for the gear, the cooling water and air for cutting treatment through pouring holes and light for illumination the operation area. Dental burs and other attachments according to ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011) will be used with the MASTERmatic LUX handpieces.

The different electrical motors (i.e. INTRAmatic LUX KL 702) utilized with the MASTERmatic LUX handpieces, are registered with the different dental treatment units (K103027 in the case of INTRAmatic LUX KL 702). Based on the INTRAmatic connection that meets the ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) standard the MASTERmatic LUX handpieces fit with any electrical dental motor which is produced in accordance to this standard. The different electrical motors will not be delivered together with the MASTERmatic LUX handpieces. The electrical motors carry the energy for the gear, the cooling water and air for cutting treatment and light for illumination from the dental treatment unit to the MASTERmatic LUX handpieces.

Accessories:

Additionally most models of the MASTERmatic LUX handpieces will be supplied with an exchange filter to filter the spray water in the water lines inside of the dental electrical-driven handpiece. For the assembly and dismantling of the exchange filter, a supporting tool is also included.

Furthermore there is a jet needle supplied with the MASTERmatic LUX handpieces. By using this part the operator is able to clean the spray holes in the head of the product.

The straight handpiece MASTERmatic LUX M10 L is equipped with a drill bit stop and a hook for removal of the drill.

Dental burs and other attachments that meets the ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011) standard may be inserted into the chuck system of the MASTERmatic LUX handpieces for applicable cutting operations based on the intended use.

Mechanism of Action:

The MASTERmatic LUX dental handpieces are electrical-driven handpieces which will be supplied with energy, water, air and light through the tube and the electrical motor of a dental treatment unit. Based on the speed adjusted in the dental treatment unit the handpiece bur rotates up to 200,000 rpm. The MASTERmatic LUX handpieces interact with the patient through a rotating bur with the patient teeth according to the intended use.

Statement of Intended Use:

The MASTERmatic LUX handpieces are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The MASTERmatic LUX handpieces function in a manner similar to and are intended for the same use as the A-dec 1 W&H Synea Air-Driven Highspeed Handpieces (K070663) marketed by W & H DENTALWERK BUERMOOS GMBH. The MASTERmatic LUX handpieces are similar to the predicate device (K070633) in that they are dental electrical-driven handpieces for the use by a trained professional in the field of general dentistry. The MASTERmatic LUX handpieces are substantially equivalent in design, application and function to the predicate device (K070663). Both the A-dec 1 W&H Synea Air-Driven Highspeed Handpieces (K070663) and the

MASTERmatic LUX handpieces are reusable and ergonomically shaped. The devices can be sterilized by the steam autoclave method and they are both provided with a fiber optic light system. Dental burs and cutters (with straight handpiece shank or with contra-angle shank) according to ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011) can be used for both, the MASTERmatic LUX handpieces and the A-dec 1 W&H Synea Air-Driven Highspeed Handpieces (K070663). In addition both handpiece types, the MASTERmatic LUX handpieces and the A-dec 1 W&H Synea Air-Driven Highspeed Handpieces (K070663) are equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) and receive the energy for the gear, the cooling water and air for cutting treatment through the tube and the specific electrical motor connected to a dental unit as the mechanism of action.

The MASTERmatic LUX handpieces differ from the A-dec 1 W&H Synea Air-Driven Highspeed Handpieces (K070663) in dimensions, fiber optic and lubrication. The MASTERmatic LUX handpieces are only available with a fiber optic light system for illumination of the operation area. Both devices use their own lubrication and have small differences in the dimensions (see Table - Summary of the Technological Characteristics).

The differences do not render the device NSE because the performance tests demonstrate that the differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate and show that the device is equivalent to the predicate.

¶

Summary of the Technological Characteristics:

Descriptive Information	MASTERmatic LUX	A-dec I W&H Synea Air-Driven Highspeed Handpiece, Models TA-98, TA-97 I A-dec I W&H Synea Handpiece Attachment, Models WA-99LT, WA-86LT, WA-66LT, WA-56LT, HA-43LT (K070663) (W & H DENTALWERK BUERMOOS GMBH)
Intended Use 1 Indications for Use	The MASTERmatic LUX handpieces are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.	The A-dec1W&H Synea Handpiece Attachment is powered by either an air-motor or electric micromotor for use in general dentistry. This device is designed for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth.
Functional Principle	Through the micro motor connected to the dental treatment unit the straight and contra-angle handpieces equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receives the energy, the cooling water and air for treatment and the light for illumination the operating area.	Through the micro motor connected to the dental treatment unit the straight and contra-angle handpieces equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receives the energy, the cooling water and air for treatment and the light for illumination the operating area.
Air 1 water ports	Internal Spray	Internal Spray
Fiberoptics	With built-in light system	With and without built-in light system
Dimensions	Headsize-Height: Up to 13,6 mm Headsize-Diameter: Up to 10,2 mm Length: Up to 95,9 mm	Headsize-Height (with bur): Up to 20,8 mm Headsize-Diameter: Up to 9,5 mm Length: Unknown
Type of chuck	Push Button, Twist-tension Chuck	Push Button, Twist-tension Chuck

Rotary Instruments	For Burs, Cutters and other attachments (with straight handpiece shank or with contra-angle shank) according to ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011).	For Burs, Cutters and other attachments (with straight handpiece shank or with contra-angle shank) according to ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011).
Speed Range	Up to 200,000 rpm	Up to 200,000 rpm
Direct patient-contacting portions of the device	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system - ISO 10993-1:2009)	Unknown
Indirect patient-contacting portions of the device (water 1 air lines)	Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system - ISO 10993-1:2009)	Unknown
Light Intensity	Approx. 25,000 LUX	Approx. 25,000 LUX
Bur retention force	Min. 22 N (45 N straight handpieces)	Unknown
Compliance to Standards	Complies with: ISO 14457 (Dentistry - Handpieces and motors - ISO 14457:2012) ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011) ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)	Complies with: ISO 14457 (Dentistry - Handpieces and motors - ISO 14457:2012) ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011) ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)
Lubricant	KaVo QUATTROcare (K071288)	Unknown (Own Lubricant from W&H)
Sterilization	Sterilizable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device - ISO 17665-1:2006)	Sterilizable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device - ISO 17665-1:2006)

Non-Clinical Test Data:

Performance bench testing according to the international standards for dental gear-driven handpieces have been conducted to determine the conformance to the state of the art. Biocompatibility and sterilization studies have been completed which demonstrate that the MASTERmatic LUX handpieces are well-suited for their intended use.

The performance of the MASTERmatic LUX handpieces has been verified utilizing the following standards:

- ISO 3964 - 1982-12-00 - Dentistry - Coupling dimensions for handpiece connectors
- ISO 1797-1 - 2011-08-00 - Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals
- ISO 10993-1 - 2009-10-00 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system
- ISO 14457 - 2012-09-15 - Dentistry - Handpieces and motors
- ISO 17665-1 - 2006-08-15 - Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device

Clinical Test Data:

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the tests according to the international standards for dental gear-driven handpieces, the biocompatibility and sterilization studies and the similar technological 1 performance characteristics as compared to the predicate device, the performance of the MASTERmatic LUX handpieces is deemed to be substantially equivalent to the predicate device.