DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 17, 2017

Kaltenbach & Voigt GmbH
Stefan Trampler
Director Regulatory Affairs
Bismarckring 39
Biberach, 88400
GERMANY

Re: K163239
Trade/Device Name: SMARTmatic
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EFA
Dated: February 14, 2017
Received: February 15, 2017

Dear Stefan 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,

Michael J. Ryan -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)*

K163239

Device Name
SMARTmatic

Indications for Use *(Describe)*

The SMARTmatic 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.

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KaVo. Dental Excellence.

Section V - 510(k) Summary

Submitter:

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Date Summary Prepared: February 14, 2017

Device Name:

- Trade Name - ***SMARTmatic***
- Common Name - Handpiece, belt and/or gear driven, dental
- Classification Name - Dental handpiece and accessories, per 21 CFR § 872.4200
- Device Class - Class I
- Product Code - EFA

Devices for Which Substantial Equivalence is Claimed:

MASTERmatic LUX (K143465) marketed by Kaltenbach & Voigt GmbH.

- Trade Name - MASTERmatic LUX
- Common Name - Handpiece, belt and/or gear driven, dental
- Classification Name - Dental Handpiece and Accessories, per 21 CFR § 872.4200
- Device Class - Class I
- Product Code - EFA

Device Description:

The ***SMARTmatic*** electrical-driven handpieces listed in the table below 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. The devices can be sterilized by the steam autoclave method. Through the tube and the electrical motor connected to a dental unit, the ***SMARTmatic*** 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. Dental burs and other attachments will be used with the ***SMARTmatic*** handpieces per ISO 1797-1:2011 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals).

Device	Detailed Description
SMARTmatic S10	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a straight handpiece for the use of dental burs and other attachments according to ISO 1797-1.

SMARTmatic S10 K	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a straight handpiece with a reduced diameter at the back of the handpiece (K) for the use of dental burs and other attachments according to ISO 1797-1.
SMARTmatic S10 S	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a straight handpiece with external spray (S) for the use of dental burs and other attachments according to ISO 1797-1.
SMARTmatic PROPHY S19	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a straight handpiece for the use of prophylaxis heads with a Doriot connector according to ISO 14457.
SMARTmatic PROPHY S19 K	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a straight handpiece with a reduced diameter at the back of the handpiece (K) for the use of prophylaxis heads with a Doriot connector according to ISO 14457.
SMARTmatic S20	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece for the use of dental burs and other attachments according to ISO 1797-1.
SMARTmatic S20 K	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece with a reduced diameter at the back (K) of the handpiece for the use of dental burs and other attachments according to ISO 1797-1.
SMARTmatic S20 S	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece with external spray (S) for the use of dental burs and other attachments according to ISO 1797-1.
SMARTmatic S80 K	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece with a reduced diameter at the back of the handpiece (K) for the use of dental burs and other attachments according to ISO 1797-1.
SMARTmatic ENDO S81	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece for the use of dental burs and other attachments according to ISO 1797-1 and has a ratio of 8:1 for endodontic purposes.
Elements 8:1	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece for the use of dental burs and other attachments according to ISO 1797-1 and has a ratio of 8:1.
SMARTmatic ENDO S321	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece for the use of dental burs and other attachments according to ISO 1797-1 and has a ratio of 32:1 for endodontic purposes.

SMARTmatic S53	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece for the use of dental burs and other attachments according to ISO 1797-1 for prophylaxis and endodontic purposes.
SMARTmatic PROPHY S31	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece for the use of prophy cups or polishing brushes according to ISO 13295 for support (spindle) type 5.
SMARTmatic PROPHY S31 K	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece and has a reduced diameter at the back of the handpiece (K) for the use of prophy cups or polishing brushes according to ISO 13295 for support (spindle) type 5.
SMARTmatic PROPHY S33	This model attaches to a dental motor according to ISO 14457 with coupling per ISO 3964 and represents a contra-angle handpiece for the use of prophy cups or polishing brushes according to ISO 13295 for support (spindle) type 5.

Per the Guidance for Industry and FDA Staff; Bundling Multiple Devices or Multiple Indications in a Single Submission, dated June 22, 2007, Kaltenbach and Voigt GmbH is bundling the ***SMARTmatic*** models listed above as the models do not differ significantly in purpose, design, materials, energy source, function or any other feature related to safety and effectiveness. The device description and intended use are identical for all configuration models. All critical components within the ***SMARTmatic*** dental handpieces are common. The minor differences between the models are cosmetic in nature such as straight or contra-angle design, size / shape of the handpiece, with / without external water spray, and bur movement.

The different electrical motors (i.e. INTRAmatic LUX KL 702) utilized with the ***SMARTmatic*** 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 3964:1982 standard (Dentistry - Coupling dimensions for handpiece connectors), the ***SMARTmatic*** 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 ***SMARTmatic*** *handpieces*. The electrical motors carry the energy for the gear, the cooling water and air for cutting treatment from the dental treatment unit to the ***SMARTmatic*** *handpieces*.

Accessories:

Additionally, the ***SMARTmatic*** handpiece models equipped with external spray will be supplied with a jet needle. The straight handpieces ***SMARTmatic S10 / S10 K / S10 S*** are equipped with a drill bit stop and a hook for removal of the drill. Dental burs and other attachments that meets the ISO 1797-1:2011 standard (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals) may be inserted into the chuck system of the ***SMARTmatic*** handpieces for applicable cutting operations based on the intended use. The Accessories are for informational purposes only.

Jet Needle:

- *Description of the Principle of Operation / Mechanism of Action – The Jet Needle is used to clean the spray lines of the devices when necessary.*
- *A description of proposed conditions of use / How used with the SMARTmatic – The operator will use the Jet Needle by inserting it into the water line to unclog any blockage.*

***Drill Bit Stop* (Bur Stop) (*SMARTmatic S10 / S10 K / S10 S*):**

- *Description of the Principle of Operation / Mechanism of Action – The Drill Bit Stop (Bur Stop) is used when using contra-angle burs in a straight handpiece.*
- *A description of proposed conditions of use / How used with the SMARTmatic – The operator will open the handpiece chuck then insert the bur stop in the chuck. The operator will then press the contra-angle bur onto the bur stop and then close the clamping ring making sure that it is firmly seated.*

***Hook* (*SMARTmatic S10 / S10 K / S10 S*):**

- *Description of the Principle of Operation / Mechanism of Action – The Hook is used by the operator when removing the Bur Stop.*
- *A description of proposed conditions of use / How used with the SMARTmatic – When a contra-angle bur is used that requires a Drill Bit Stop (Bur Stop), the Hook is required to remove the Bur Stop out of the chuck after use.*

Mechanism of Action:

The ***SMARTmatic*** dental handpieces *are* electrical-driven handpieces which will be supplied with energy, water and air 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 40,000 rpm. The ***SMARTmatic*** handpieces interact with the patient through a rotating bur with the patient teeth according to the intended use.

Statement of Intended Use:

The ***SMARTmatic*** *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 ***SMARTmatic*** handpieces function in a manner similar to and are intended for the same use as the MASTERmatic LUX handpieces (K143465) marketed by Kaltenbach & Voigt GmbH. The ***SMARTmatic*** handpieces are similar to the predicate device (K143465) in that they are dental electrical-driven handpieces for the use by a trained professional in the field of general dentistry. The ***SMARTmatic*** handpieces are substantially equivalent in design, application and function to the predicate device (K143465). Both the MASTERmatic LUX handpieces (K143465) and the ***SMARTmatic*** handpieces are reusable and ergonomically shaped. The devices can be sterilized by the steam autoclave method. 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 ***SMARTmatic*** handpieces and the MASTERmatic LUX handpieces (K143465). In addition, both handpiece types, the ***SMARTmatic*** handpieces and the MASTERmatic LUX handpieces (K143465) 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 ***SMARTmatic*** handpieces differ from the MASTERmatic LUX handpieces (K143465) in dimensions, speed range, type of chuck, fiber optics and the supply of spray. The ***SMARTmatic*** handpieces are only available with external spray / no spray (according to the model). The ***SMARTmatic*** handpieces are not available with a fiber optic light system. The speed range of the ***SMARTmatic*** handpieces which is up to 40,000 rpm differs from the speed range of the MASTERmatic LUX handpieces (200,000 rpm). Some models of the ***SMARTmatic*** handpieces are also available with a different type of chuck. Both devices have small differences in the dimensions (see Table - Summary of the Technological Characteristics).

The performance tests demonstrate that the differences in technological characteristics do not raise different concerns regarding substantial equivalence to the predicate device. Hence, the ***SMARTmatic*** handpieces are substantial equivalent to the MASTERmatic LUX handpieces.

In summary, the ***SMARTmatic*** handpieces with the indications for use and intended use described in this submission are substantially equivalent to the MASTERmatic LUX handpieces cleared under K143465. It also satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: (1) Indications for Use, (2) Technological Characteristics and (3) Performance Data. The new device does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantial equivalent.

Summary of the Technological Characteristics:

Descriptive Information	**SMARTmatic**	**MASTERmatic LUX (K143465) from Kaltenbach & Voigt GmbH**
Indications for Use		
Indications for Use	The SMARTmatic 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 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.
Device Design		
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.

Operational Modes	N/A - Standard	N/A - Standard
Air / water ports	No Spray / External Spray	Internal Spray
Fiberoptics	Without light system	With built-in light system
Dimensions	Head size-Height: Up to 13,6 mm Head size-Diameter: Up to 9,8 mm Length: Up to 93,4 mm	Head size-Height: Up to 13,6 mm Head size-Diameter: Up to 10,2 mm Length: Up to 95,9 mm
Type of chuck	Push Button, Twist-tension Chuck, Snap-on & Screw-in	Push Button, Twist-tension Chuck
Coupling Dimensions	Dimensions comply with ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)	Dimensions comply with ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)
Accessories	Jet Needle, Drill Bit Stop (Bur Stop), Hook, Dental Burs and Prophylaxis Heads	Jet Needle, Drill Bit Stop (Bur Stop), Hook and Dental Burs
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).
Composition of Materials		
Direct patient-contacting portions of the device	All materials for the SMARTmatic models are listed in the tables below including chemical composition of the waterlines and the 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)	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)
Indirect patient-contacting portions of the device (water / air lines)	All materials for the SMARTmatic models are listed in the tables below including chemical composition of the waterlines and the 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)	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)

Technical Specifications		
Chuck Design	Push Button, Twist-tension Chuck, Snap-on & Screw-in	Push Button, Twist-tension Chuck
Light Intensity	N/A	25,000 Lux
Bur Retention Force	Min. 22 N (45 N straight handpieces)	Min. 22 N (45 N straight handpieces)
Bur Extraction Force	15N - 52N	15N - 52N
Maximum Air Pressure	29 psi	29 psi
Maximum Water Pressure	29 psi	29 psi
Speed Range (RPM's)	Up to 40,000 rpm	Up to 200,000 rpm
Conformance Standards (Handpieces and Motors)	ISO 14457 (Dentistry - Handpieces and motors - ISO 14457:2012)	ISO 14457 (Dentistry - Handpieces and motors - ISO 14457:2012)
Conformance Standards (Shanks)	ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011)	ISO 1797-1 (Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals - ISO 1797-1:2011)
Conformance Standards (Coupling Dimensions)	ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)	ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)
Conformance Standards (Hose Connections)	N/A – For air driven handpieces only.	N/A – For air driven handpieces only.
Sterilization	Sterilisable 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)	Sterilisable 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)
Lubricant		
	KaVo QUATTROcare (K071288)	KaVo QUATTROcare (K071288)

Non-Clinical Test Data:

Performance bench testing according to international standards for dental handpieces and accessories (handpiece, belt and/or gear driven) has been conducted to determine conformance. Biocompatibility and sterilization studies has been completed for the applicable components. Hence the ***SMARTmatic*** demonstrates substantial equivalence.

The performance of the ***SMARTmatic*** *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 7405 Second edition 2008-12-15 - Dentistry - Evaluation of biocompatibility of medical devices used in dentistry / 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
- AAMI ANSI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 Comprehensive Guide To Steam Sterilization And Sterility Assurance In Health Care Facilities
- Guidance for Industry and FDA Staff - Dental Handpieces - Premarket Notification [510(k)] Submissions - 2007-05-02

Clinical Test Data:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion:

Based on a comparison of intended use, indications, technological characteristics, principle of operation, features and performance data, the ***SMARTmatic*** is deemed to be substantially equivalent to the predicate device.