DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 21, 2017

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

Re: K163317
Trade/Device Name: ELECTROmatic
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EBW
Dated: November 22, 2016
Received: November 23, 2016

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)*
K163317

Device Name
ELECTROmatic

Indications for Use *(Describe)*
The ELECTROmatic is intended to convert pneumatic output from a dental treatment center to electrical energy to drive the COMFORTdrive motor handpiece and the INTRA LUX KL 703 LED motor for operation of electrically-driven dental handpieces. This device is 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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K163317

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: Jan, 27th 2017

Device Name:

- Trade Name - ***ELECTROmatic***
- Common Name - Dental Handpiece and Accessories
- Classification Name - Dental Handpiece and Accessories, per 21 CFR § 872.4200
- Device Class - Class I
- Product Code - EBW

Devices for Which Substantial Equivalence is claimed:

ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027) marketed by Kaltenbach & Voigt GmbH.

- Trade Name - ELECTROtorque TLC 4893 with INTRAmatic KL 702
- Common Name - Dental Handpiece and Accessories
- Classification Name - Dental Handpiece and Accessories, per 21 CFR § 872.4200
- Device Class - Class I
- Product Code - EBW

Device Description:

The ***ELECTROmatic*** dental control unit is a stand-alone system for operating electrically-driven KaVo handpieces. External power supply provides electric power to the unit. The 4-hole tubing connected to the unit supplies chip /cooling air, water and pressure signal. The speed of the electric handpiece is controlled by air pressure. The control unit is positioned close to a treatment unit at the location preferred by the dentist. The ***ELECTROmatic*** system consists of a base unit with a motor hose, an electrical motor, a transformer, and a power cord.

Per the Guidance for Industry and FDA Staff; Bundling Multiple Devices or Multiple Indications in a Single Submission, dated June 22, 2007, Kaltenbach & Voigt GmbH is bundling the ***ELECTROmatic*** models listed below as the models do not differ significantly in purpose, design, materials, energy source, function or any other feature related to substantial equivalence. The device description and intended use are identical for all models listed below. The differences between the models and mounting configurations are cosmetic in nature such as size/shape of the device, length of the tubings, amount of motors, design of display, etc. All critical components within the ***ELECTROmatic*** are common.

The ***ELECTROmatic*** is available in the following models:

ELECTROmatic M/C (M-S, M-L, C-S, C-L)	This model represents the basic model available with either the INTRA LUX KL 703 LED motor (M) or the COMFORTdrive (C). Both configurations can be equipped with a short tubing (S) or long tubing (L).
ELECTROmatic PM/PC (PM-S, PM-L, PC-S, PC-L)	This model represents the push button version (P) available with either the INTRA LUX KL 703 LED motor (M) or the COMFORTdrive (C). Both configurations can be equipped with a short tubing (S) or long tubing (L).
ELECTROmatic TM (TM-S, TM-L)	This model represents the touch display version (T) equipped with the INTRA LUX KL 703 LED motor (M). This configurations can be equipped with a short tubing (S) or long tubing (L).
ELECTROmatic TMM/TMC (TMM-S, TMM-L, TMC-S, TMC-L)	This model represents the touch display version (T) available with either two INTRA LUX KL 703 LED motors (MM) or one INTRA LUX KL 703 LED motor and one COMFORTdrive (MC). Both configurations can be equipped with a short tubing (S) or long tubing (L).

The various mounting configurations for the ***ELECTROmatic*** are illustrated within the instructions for use. The differences between the models are the ELECTROmatic TM and ELECTROmatic TMM are the premier level devices and ELECTROmatic M/C and PM/PC are the mid-level devices.

Accessories:

Optional accessories (devices) that are attached to the ***ELECTROmatic*** are part of this submission and have already been cleared by the FDA. These optional accessories (devices) can be attached to the ***ELECTROmatic*** as indicated in their respective 510(k) summary statements. They are also attached to the predicate device (ELECTROtroque TLC 4893 with INTRAmatic KL 702) marketed by Kaltenbach & Voigt GmbH. Below are the accessories of the ***ELECTROmatic:***

Accessory	Product Code	Comment
INTRA LUX KL 703 LED (motor)	EBW	FDA cleared under K103027
COMFORTdrive (motor handpiece)	EIA	FDA cleared under K080677

Principle of Operation / Mechanism of Action:

The ***ELECTROmatic*** device is a software-driven device. The software controls the following features: (1) Motor control, (2) Motor start / stop behavior, (3) Motor speed, (4) Motor performance, (5) Measuring power consumption, (6) Monitoring power consumption, and (7) SAFEdrive. The SAFEdrive software feature monitors the power consumption of electrical hand pieces to reduce the probability or severity of overheating, thus minimizing the risk of burns to the patient. The user can navigate through the software menu via the control panel. The electrical low-voltage motor (INTRA LUX KL 703 LED) and the COMFORTdrive motor handpiece are connected onto the KaVo specific tubing of the ***ELECTROmatic***. The speed of the motor / motor handpiece is controlled by air pressure of the dental treatment center. The converted pneumatic output signal (electrical energy) from a dental treatment center drives either the motor to operate

an electrically-driven dental handpiece or the COMFORTdrive motor handpiece. Electrically-driven dental handpieces, which conform to ISO 3964, can be attached on the motor.

Statement of Intended Use:

The ***ELECTROmatic*** is intended to convert pneumatic output from a dental treatment center to electrical energy to drive the COMFORTdrive motor handpiece and the INTRA LUX KL 703 LED motor for operation of electrically-driven dental handpieces. This device is designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The ***ELECTROmatic*** function in a manner similar to and is intended for the same use as the ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027) marketed by Kaltenbach & Voigt GmbH. The ***ELECTROmatic*** is similar to the predicate device (K103027) in that it is a software driven dental control unit consisting of a base unit with a motor hose, an electrical motor, a transformer and a power cord. Both the ***ELECTROmatic*** and the ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027) have a motor connection for dental handpieces which are equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) and they are intended to be used by a trained professional in the field of general dentistry. The ***ELECTROmatic*** is substantially equivalent in design, technological characteristics, application and function to the predicate device (K103027). Both the ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027) and the ***ELECTROmatic*** have the same principle of operation and the devices can be attached to a dental treatment unit using the same water and air system. The software in the ***ELECTROmatic*** as well as the software in the ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027) control the following features: (1) Motor control, (2) Motor start / stop behavior, (3) Motor speed, (4) Motor performance, (5) Measuring power consumption, (6) Monitoring power consumption, and (7) SAFEdrive.

The ***ELECTROmatic*** differs from the ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027) in that they have different technological characteristics (motor / motor tubings, user interface, display and media). These differences are shown in the table below (Summary of the Technological Characteristics). The ***ELECTROmatic*** can also be equipped with the COMFORTdrive motor handpiece and the motor tubings can be removed via a quick connector. A TFT / touch display can be selected for the ***ELECTROmatic***. An integrated valve unit supports the two tubings models with media (air, spray air, spray water).

The performance tests demonstrate that the differences in technological characteristics do not raise different concerns regarding substantial equivalence to the predicate device. Hence, the ***ELECTROmatic*** is substantial equivalent to the ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027) marketed by Kaltenbach & Voigt GmbH.

In summary, the ***ELECTROmatic*** indications for use described in this submission is substantially equivalent to the ELECTROtorque TLC 4893 with INTRAmatic KL 702 cleared under K103027. 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	ELECTROtorque TLC 4893 with INTRAmatic KL 702 (K103027)	ELECTROmatic
Indications for Use	The ELECTROtorque TLC 4893 is intended to convert pneumatic output from a dental treatment center to electrical energy to drive the INTRAmatic KL 702 motor for operation of electrically-driven dental handpieces. They are designed for use by a trained professional in the field of general dentistry	The ***ELECTROmatic*** is intended to convert pneumatic output from a dental treatment center to electrical energy to drive the COMFORTdrive motor handpiece and the INTRA LUX KL 703 LED motor for operation of electrically-driven dental handpieces. This device is designed for use by a trained professional in the field of general dentistry
Device Components	Control unit with hose and electrical motor	Control unit with hose and electrical motor
Installation	Attached to a dental treatment center	Attached to a dental treatment center
Power and Utility Supply	120V/230V AC electrical supply, compressed air and water provided from unit	120V/230V AC electrical supply, compressed air and water provided from unit
Compatibility	Compatible with industry standard dental hose connector for turbines	Compatible with industry standard dental hose connector for turbines
User Interface	Membrane keys	Foot switch, touch keys / screen
Display	Dot matrix display	TFT / touch display
Compatible Motors	INTRAmatic KL 702	INTRA LUX KL 703 LED COMFORTdrive
Motor Tubings	Fixed to the unit	Quick connector, removable
Water System	Water is supplied from unit	Water is supplied from unit
Media (air, spray air, spray water)	Single hose connections	Integrated valve unit
Cleaning System	Cleaning System is supplied from unit	Cleaning System is supplied from unit
Software	Main part of the software is the KaVo motor control algorithm, which is controlling: - Motor control - Motor start / stop behavior - Motor speed - Motor performance - Measuring power consumption - Monitoring power consumption (SAFEdrive function)	Main part of the software is the KaVo motor control algorithm, which is controlling: - Motor control - Motor start / stop behavior - Motor speed - Motor performance - Measuring power consumption - Monitoring power consumption (SAFEdrive function)
Intended Users	Dentists, Dental Hygienists	Dentists, Dental Hygienists

Non-Clinical Test Data:

Performance bench testing according to international standards has been conducted to determine conformance. Biocompatibility and sterilization studies has been completed for the applicable components. Hence the ***ELECTROmatic*** demonstrates substantial equivalence.
The performance of the ***ELECTROmatic*** has been verified utilizing the following standards:

- ISO 9168 - 2009-07-15 - Dentistry - Hose connectors for air driven dental handpieces
- ISO 14457 First edition 2012-09-15 – Dentistry – Handpieces and motors
- IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007))
- IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirements for safety; Collateral standard: Electromagnetic compatibility; Requirements and tests (IEC 60601-1-2:2007 / EN 60601-1-2:2007)
- ANSI/AAMI ES60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (ANSI/AAMI ES60601-1: 2005 / A2:2010)
- IEC 62304 - Medical device software - Software life cycle processes (IEC 62304:2006 – First edition)
- 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 10993-1 - 2009-10-00 - Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system

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 ***ELECTROmatic*** is deemed to be substantially equivalent to the predicate device.