DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 8, 2016

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

Re: K161488
     Trade/Device Name: ESTETICA Dental Treatment Unit and Accessories
     Regulation Number: 21 CFR 872.6640
     Regulation Name: Dental Operative Unit and Accessories
     Regulatory Class: Class I
     Product Code: EIA
     Dated: November 4, 2016
     Received: November 8, 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 and Part 809); 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 and Part 809), 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,

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

Indications for Use

510(k) Number *(if known)*

K161488

Device Name

ESTETICA Dental Treatment Unit and Accessories

Indications for Use *(Describe)*

The ESTETICA Dental Treatment Unit and Accessories are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. The ESTETICA Dental Treatment Unit and Accessories 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.

Section V - 510(k) Summary

Submitter:

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Date Summary Prepared: December 5, 2016

Device Name:

- Trade Name - ***ESTETICA Dental Treatment Unit and Accessories***
- Common Name - Unit, Operative Dental
- Classification Name - Dental Operative Unit and Accessories, per 21 CFR § 872.6640
- Device Class - Class I
- Product Code - EIA

Devices for Which Substantial Equivalence is claimed:

TENEO Dental Treatment Unit and Accessories marketed by Sirona Dental Systems GmbH (K151045).

- Trade Name - TENEO Dental Treatment Unit and Accessories
- Common Name - Unit, Operative Dental
- Classification Name - Dental Operative Unit and Accessories, per 21 CFR § 872.6640
- Device Class - Class I
- Product Code – EIA, EBW

Device Description:

The ***ESTETICA Dental Treatment Unit and Accessories*** serves as a base that includes components to deliver air, water, electrical power, and vacuum to dental handpieces, instruments, and accessories. The device includes a patient chair, foot control, dentist element, assistant element and a water unit. The unit may also include a dental operating light and a monitor. Various handpieces and accessories can be added to the ***ESTETICA Dental Treatment Unit and Accessories***. These include, but not limited to, pneumatic handpieces, electric motors with handpieces, scalers, intra-oral cameras, curing lights, air/water syringes and SE and HVE vacuum instruments.

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 ***ESTETICA Dental Treatment Unit and Accessories*** 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 delivery head, mount arms, upholsteries, instrument hangers, etc. which are listed in the Comparison Table below. All critical components within the **ESTETICA Dental Treatment Unit and Accessories** are common.

The **ESTETICA Dental Treatment Unit and Accessories** are available in the following models which are offered in various mounting configurations:

> ➢ ESTETICA E70 Vision T
> ➢ ESTETICA E70 Vision C
> ➢ ESTETICA E70 Vision S
> ➢ ESTETICA E80 Vision T
> ➢ ESTETICA E80 Vision C
> ➢ ESTETICA E50 Life TM
> ➢ ESTETICA E50 Life S

The designation letters listed at the end of each model represents the style of delivery as identified below.

> ➢ *T/TM = Table/Table Mount: The handpiece/instrument tubing's hang below the dental unit.*
> ➢ *C = Cart: Cart mounted dental unit.*
> ➢ *S = Loops: The handpiece/instrument tubing's loops above the dental operative unit.*

COMPARISON TABLE

Feature	KaVo ESTETICA E80 Vision	KaVo ESTETICA E70 Vision	KaVo ESTETICA E50 Life
Dentist element			
Dentist element	*1: T-Table* *2: Cart*	*1: T-Table* *2: Whip arm* *3: Cart*	*1: T-Table* *2: Whip arm*
Control element	*Control element - Touch display*	*Control element - Touch display*	*Control element - Display and push buttons*
Instrument holder	*6*	*5 (6 optional)*	*5 (6 optional)*
1 x Multifunctional handpiece	*Standard*	*Optional*	*Optional*
1 x Three function handpiece	*N/A*	*Standard*	*Standard*
Spray heating for instruments	*Standard*	*Standard*	*Standard*
Normtrays	*Standard*	*Standard*	*Standard*
Assistant element			
Control element	*Glass touch panel*	*Glass touch panel*	*Control element with push buttons*
Removable instrument holder	*Standard*	*Standard*	*N/A*

Swivel- and height adjustable	Standard	Standard	Standard
Unit body			
Instrument rinsing	Integrated hygiene center	Integrated hygiene center	Attached hygiene center
Hot water boiler for mouth glass filling	Standard	Standard	Standard
Spittoon (Glass or Porcelain)	Motorized	Manual is Standard, Motorized is optional	Manual
Unit body color	Metallic and uni	Uni	Dental white
Patient chair			
Patient chair	Suspended chair	Suspended chair	Floor-mounted chair
Motorized horizontal movement and seat elevation	Standard	N/A	N/A
Backrest Progress	Standard	Standard	Standard
Backrest Comfort	Standard	Standard	N/A
Double-jointed headrest with rotary control knob with mechanical clamp	N/A	Standard	Standard
Double-jointed headrest with rotary control knob with pneumatic clamp	Standard	Optional	N/A
Motorized head rest	Optional	Optional	N/A
Comfort head cushion	Optional	Optional	Optional

The various mounting configurations for the **ESTETICA Dental Treatment Unit and Accessories** are illustrated within the use and care manuals. The differences between the models are the ESTETICA 70 Vision and ESTETICA E80 Vision are the premier level dental operative units and the ESTETICA E50 Life is the mid-level dental operative unit.

Accessories:

Optional accessories (devices) that are integrated / attached to the ESTETICA dental operative units have already been cleared by the FDA. Below are the accessories of the **ESTETICA Dental Treatment Unit:**

Accessory	Product Code	Comment
INTRA LUX KL 703 LED (motor)	EBW	FDA cleared under K103027
INTRA LUX S600 LED (motor)	EBW	FDA cleared under K140308
Multi-Function Handpieces (syringe)	ECB	Class I, exempt under 21 CFR 872.4565
Three-Function Handpieces (syringe)	ECB	Class I, exempt under 21 CFR 872.4565
CONEXIO (software)	EIA	Dental Operative Units and accessories

ERGOcam One (camera)	EIA	Dental Operative Units and accessories / Only used for patient communication, not for diagnosis
Turbines	EFB	FDA cleared under K073478, K130560
Eletrical Handpieces	EFA	FDA cleared under K073478, K143465
SONICflex (ultrasonic scaler)	ELC	FDA cleared under K080089
Satelec Mini LED (curing light)	EBZ	FDA cleared under K032465
KaVolux 540 LED (dental light)	EAZ	Class I, exempt under 21 CFR 872.4630
DIAGNOcam 2170	NTK	FDA cleared under K123402
PiezoLED (electrical scaler)	ELC	FDA cleared under K093000, K132443, K140990
MULTIflex couplings	EFB	FDA cleared under K073478, K130560

Principle of Operation / Mechanism of Action:

The **ESTETICA Dental Treatment Unit and Accessories** is designed to bring a patient into an ergonomic and comfortable position to perform dental treatment procedures. For this purpose, the patient chair can be brought into an appropriate position, either by activating the chair positioning motors or by recalled programmed positions set by the user. The headrest is adjusted manually by motor according to patient height and the area in the patient's oral cavity to be treated. The treatment is performed by the instruments placed in the designated instrument holders. The required parameters (e.g. power, torque, speed, cooling media) can be adjusted via a panel / touch panel or recalled from settings programmed by the user beforehand. After taking an instrument from its respective holder, it can be activated via the foot control. To place dental hand instruments and materials required during treatment tray surfaces are provided.

To dispose fluids and particles deriving from the oral cavity during treatment, suction hoses with attached instruments are provided on the assistant element. Selecting the suction instrument activates the vacuum. Also, a cuspidor bowl is available for patient rinse. The cuspidor can be manually swiveled towards the patient chair. The cuspidor bowl automatically returns after use to ensure that the patient does not collide with it during chair movements.

An operating light providing illumination to the oral cavity can be switched on via the panel / touch screen or is operated automatically in accordance with preset adjustments in connection with the pre-programmed chair positions. It can be also switched on/off via a no-touch sensor which recognizes when the hand is moved there. Most chair and instrument related functions can be activated hands-free via foot control. The foot control is also available with wireless transmission. The panel / touch screen style user interface applies context-sensitivity; i.e. according to the actual operational state, varying buttons and functions are displayed and provided for use. Prescribed procedures and supporting components apply to facilitate infection control and maintaining water quality, such as automated suction hose and instrument hose purge, automatic dosage of waterline treatment and suction cleaning agents, integrated cleaning adapters for hoses. Water supply is also possible using self-containing systems.

As an option the **ESTETICA Dental Treatment Unit and Accessories** can be equipped with an endodontic and / or surgery function. The endodontic function has an electronic torque limitation with variable torque modes (auto reverse, auto reverse forward and torque control only). The surgery function has different program steps according to the implantation activities (pilot drilling, form drilling, tapping, placing implant, setting a closure cap, marking and free use).

Also a peristaltic pump and a NaCl bottle holder can be attached to the dentist element. The peristaltic pump prepares a sterile saline solution instead of spray water for cooling. This system connects as a "closed system" to the **ESTETICA Dental Treatment Unit and Accessories** to ensure full sterility.

ESTETICA Dental Treatment Unit and Accessories has a motor-driven headrest, which can be moved via the touch screen and a 4-way switch at the backside of the headrest. Also a standard headrest is available which can be moved via mechanical adjustment. Both types of headrest allow the following adjustments: extension / retraction to adapt to the patient's stature, tilting for maxillary / mandibular treatment. Moreover, the removable head pad with magnetic holder allows shifting / rotation of the head support.

Statement of Intended Use:

The **ESTETICA Dental Treatment Unit and Accessories** are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. The **ESTETICA Dental Treatment Unit and Accessories** are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The **ESTETICA Dental Treatment Unit and Accessories** function in a manner similar to and are intended for the same use as the TENEO Dental Treatment Unit and Accessories (K151045) marketed by Sirona Dental Systems GmbH but does have different technological characteristics. However, these different technological characteristics do not raise new concerns of substantial equivalence. The performance data and testing of the **ESTETICA Dental Treatment Unit and Accessories** demonstrates substantial equivalence to the TENEO Dental Treatment Unit and Accessories (K151045). Hence, the device is deemed to be substantially equivalent.

Summary of the Technological Characteristics:

Descriptive Information	ESTETICA Dental Treatment Unit and Accessories	TENEO Dental Treatment Unit and Accessories (K151045 - Sirona Dental Systems GmbH)
Intended Use / Indications for Use	The ESTETICA Dental Treatment Unit and Accessories are intended to supply power to and serve as a base for other dental devices and accessories by providing air, water, vacuum and low voltage electrical power to dental instruments and dental handpieces. The ESTETICA Dental Treatment Unit and Accessories are designed for use by a trained professional in the field of general dentistry.	This dental treatment unit with accessories is intended to supply power to and serve as a base for dental devices and accessories. This product includes a dental chair. The dental treatment unit is intended for use in the dental clinic environment and is used by trained dentists and/or dental assistants. The motors serve as drives for rotating and oscillating straight and contra-angle handpieces in connection with a dental treatment unit. They are used for endodontic and general dental purposes. The SPRAYVIT M multifunctional syringe is used for dental treatment with unheated air and heated water. It is also used to illuminate the preparation field.

Dentist Element	Positions	6 handpiece positions + 1 additional	6 handpiece positions + 1 additional
	Max. Motors	Up to 4 motors (electrical motors with and without light)	Up to 4 motors (electrical motors with and without light)
	User Interface	ESTETICA E70/E80 Vision: EasyTouch Display, color, plus additional several keys (foil) and Status LEDs ESTETICA E50 Life: Display, with several keys (foil) and Status LED	EasyTouch Display 7", color, plus additional 13 keys (foil) and Status LEDs
		Hands free operation with cursor control by foot control	Hands free operation with cursor control by foot control
	Syringe	Multifunctional syringe with internal heater for water and light or 3 Functional syringe without heater and light	Sprayvit M with internal heater for water and light
	Turbines	Turbines with light	Turbines with light
	Control of Coolant	Water amount controlled by the unit	Water amount controlled by the unit
		Air amount controlled by the unit	Air amount controlled by the unit
	Scaler	PiezoLED with light PIEZOsoft without light	Sirosonic TL with light
	Intraoral Camera	ERGOcam One	Sirocam AF+
	Curing Light	Mini LED (Acteon, Satelec)	Mini LED (Acteon, Satelec)
	X-ray Viewer	Panorama X-ray image viewer or small X-ray viewer	Panorama X-ray image viewer
	Endodontic	Implantology functions	Implantology functions
		Endodontic treatment functions	Endodontic treatment functions
		Integrated (E70/E80 Vision) or adapted (E50 Life) pump for saline solution	Integrated pump for saline solution
		N / A	Integrated Apex locator function
	Interfaces	USB Interface	USB Interface
Assistant Element	Positions	2/3 suction positions, 2 handpiece positions	4 handpiece positions
	User Interface	Touch pad (foil) with several keys and status LEDs	Touch pad (foil) with 12 keys and status LEDs
	Syringe	Multifunctional syringe with internal heater for water and light or 3 Functional syringe without heater and light	Sprayvit M with internal heater for water
	Curing Light	Mini LED (Acteon, Satelec)	Mini LED (Acteon, Satelec)
	Suction	Suction devices	Suction devices
		Saliva ejector	Saliva ejector
		HVE (High volume evacuator)	HVE (High volume evacuator)
		Surgical suction devices	Surgical suction devices
	Interfaces	USB interface	USB interface
		N / A	Hydrocolloid port
Chair	Patient load	ESTETICA E70/E80 Vision: 180 kg ESTETICA E50 Life: 185kg (Standard Chair) ESTETICA E50 Life: 135kg (Compact Chair)	Max. 160kg + 5 kg accessories
	Headrest	Manually operated or motorized headrest	Motorized headrest
	Upholstery	Skai upholstery	Thermo upholstery / lounge upholstery (sleek style)

	Armrest	Armrest, retractable	Armrest removable
	Switch	4-way foot-switch	4-way foot-switch
	Movement	Synchronized Backrest and seat movements	Synchronized Backrest and seat movements
		N / A	External device connection
		N / A	Massage and lumbar support function
		User programmable positions	User programmable positions
		Backrest motor driven	Backrest motor driven
		ESTETICA E80 Vision: Horizontal movement, seating bench lifting	N / A
		Seat and seat inclination motor driven	Seat and seat inclination motor driven
Water unit	Cuspidor bowl	Manually adjustable or Motor driven cuspidor bowl	Motor driven cuspidor bowl
	Amalgam separator	Amalgam separator	Amalgam separator
	Water	Connection to municipal water with safety separation via "air gap"	Connection to municipal water
	Heating	Water heater	Water heater
	Water / Suction Hose treatment	Water treatment with permanent sanitization function	Water treatment with permanent sanitization function
		Suction hose cleaning with water	Suction hose cleaning with water
		Suction hose cleaning with chemicals	Suction hose cleaning with chemicals
	Water treatment	Waterline Treatment solution	Waterline Treatment solution
	Purge	Purge function	Purge function with auto purge General
General	Operating Light	LEDview	LEDview
	Monitor	19" or 22" monitor on the light support frame	22" monitor on the tray incl. tray or 22" monitor on the light support frame
	Foot Control	Wireless Foot control available	Wireless Foot control available
		Electronic foot control	Electronic foot control
	PC Interface	Network interface	Network interface

Non-Clinical Test Data:

Performance bench testing according to international standards for dental operative units has been conducted to determine conformance in regards to:

- Biocompatibility and sterilization studies has been completed for the applicable components.
- Software documentation for moderate level of concern per the FDA Guidance Document for Software Contained in Medical Devices.
- Comparative performance testing of the functions of the integrated accessories as compared to the cleared stand-a-lone device.
- For the wireless foot pedal, software verification/validation of the functions of the foot control was conducted. Additionally, EMC testing was performed to evaluate the risk of communication loss according to IEC 60601-1-2:2007 and Electrical Safety Tests have been done according to IEC 60601-1-1:2005.

Furthermore, the performance of the **ESTETICA Dental Treatment Unit and Accessories** has been verified utilizing the following standards:

- ISO 7494-1 - 2011-08-15 - Dentistry - Dental units - Part 1: General requirements and test methods
- ISO 7494-2 - 2003-03-01 - Dentistry - Dental units - Part 2: Water and air supply
- 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 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
- ISO 14971 - Second Edition 2007-03-01 - Medical Devices - Application of risk management to medical devices

Hence the **ESTETICA Dental Treatment Unit and Accessories** demonstrates substantial equivalence.

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 **ESTETICA Dental Treatment Unit and Accessories** are deemed to be substantially equivalent to the predicate device.