



Food and Drug Administration
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July 24, 2015

Sirona Dental Systems Gmbh
% Mr. Kofi Aninakwa
Legal Services Engineer
Sirona Dental Systems, Inc.
30-30 47th Avenue, Suite 500
Long Island City, New York 11101

Re: K151045

Trade/Device Name: Teneo 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, EBW
Dated: June 15, 2015
Received: June 19, 2015

Dear Mr. Kofi Aninakwa:

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,

A handwritten signature in black ink that reads "Susan Runno DDS, MA". The signature is written in a cursive style. A faint, semi-transparent "FDA" watermark is visible behind the signature.

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): **K151045**

Device Name: **TENEO DENTAL TREATMENT UNIT AND ACCESSORIES**

Indications for Use:

The 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 hand pieces 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.

Prescription Use (Part 21 CFR 801 Subpart D)

OR

Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K151045
510(k) Summary
for
Sirona Dental Systems
TENEO Dental Treatment Unit and Accessories

1 SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
64625 Bensheim
Germany

Contact Person: Kofi Aninakwa
Telephone: 718-482-2248
Date Prepared: July 19, 2015

2 DEVICE NAME

Proprietary Names : TENEO Dental Treatment Unit and Accessories
Common/Usual Name: Unit, Operative Dental
Classification Name : Dental operative unit and accessories.
Regulation Number : 21 CFR 872.6640
Product Code : EIA, EBW
Device Class : 1

3 PREDICATE DEVICES

- C8+ DENTAL OPERATIVE UNIT WITH ACCESSORIES - (K032543)
Product Code – EIA
Regulation Number 21 CFR 872.6640
- A-DEC 200 DENTAL SYSTEM - (K102234)
Product Code – EIA
Regulation Number 21 CFR 872.6640

Sirona's C8+ is the primary predicate device for substantial equivalence as it has more similar functions as the TENEO.

4 INTENDED USE

The 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 hand pieces 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.

4.1 Contra-Indications

This dental treatment unit is not intended for operation in areas subject to explosion hazards.

This dental treatment unit is permanently installed. Operation is not permitted in mobile vehicles.

Highly immunosuppressed patients or patients with specific pulmonary diseases should not come in contact with the water of the treatment unit. The use of sterile solutions is recommended.

5 DEVICE DESCRIPTION AND FUNCTION

The TENEO dental treatment unit is a dental operating system. 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.

6 PRINCIPLES OF OPERATION

The dental treatment center 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 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 handpieces are provided on the assistant element. Picking the suction handpieces activates the vacuum. For disposal also a cuspidor bowl is available. The cuspidor can be manually swiveled towards the patient chair. The cuspidor bowl automatically returns beforehand 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 touch panel 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 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 TENE0 can integrate into a therapy package, including the endodontic and implantology functions.

The therapy package integrates electronic torque limitation and a file library, containing different current file systems and their recommended torque settings. The ApexLocator is a support function to determine the position of a file in the root canal. It can be used with an x-ray image of the tooth for root canal measurements. During the endodontic treatment, the user receives file position information. This is achieved using electrical impedance with mucosal electrode and a conductive

connection between root file and the TENE0. An acoustic signal and a diagram submit the information. Exact length measurements from the root canal file to the physiological apex (apical constriction) are not provided. The root canal has to be detected via X-ray.

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 TENE0 to ensure full sterility.

TENE0 has a motor-driven headrest, which can be moved via the touchscreen or a 4-way switch at the backside of the headrest. The motor-driven headrest allows 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. Also a mechanical adjustment of headrest tilt is possible.

Accessories

Below are the accessories of the TENE0 Dental Treatment Unit

Accessory	Product Code	Comment
Motor BL	EBW	A physical part of the operative unit
Motor BL ISO C	EBW	A physical part of the operative unit
Motor BL Implant	EBW	A physical part of the operative unit
SPRAYVIT M	ECB	Class I, exempt under 21 CFR 872.4565
SiroCam AF+	EIA	Dental Operative Units and accessories. Only used for patient communication. Not for diagnosis.
Silicone pads on either dentist or assistant element	EIA	Dental Operative Units and accessories
Removable silicone sleeves for handles	EIA	Dental Operative Units and accessories
Swiveling tray support with tray tablet attached to the water unit	EIA	Dental Operative Units and accessories
Monitor 22”	EIA	Dental Operative Units and accessories
Booster cushion for small patients	EIA	Dental Operative Units and accessories
Suction parts	EIA	Dental Operative Units and accessories
Plug ball for unoccupied instrument holder	EIA	Dental Operative Units and accessories
ApexLocator (software, file clamp and mucosal electrode)	LQY	A physical part of the operative unit
Turbines	EFB	FDA Cleared - 510(k) number - K131319
Satelec Mini LED curing light	EBZ	FDA Cleared - 510(k) number - K032465
HELIODENT Plus	EHD	FDA Cleared - 510(k) number - K083344
SIROSONIC TL ultrasonic scaler	ELC	FDA Cleared - 510(k) number - K033640
LEDview	EAZ	Class I, exempt under 21 CFR 872.4630
Dentosept P	EIA	FDA Cleared - 510(k) number K962071

7 TECHNOLOGICAL CHARACTERISTICS SUMMARY

The TENE0 Device has similar physical and technical characteristics to the predicate devices, as illustrated in the table below. C8+ is the primary predicate device.

	Device	C8+ (K032543)	A-DEC 200 (K102234)	TENE0
	Intended Use	The C8+ Dental Operative 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 unit is intended for use in the dental clinic environment and used by trained dentists and/or dental technicians and assistants.	The A-DEC 200 Dental System and accessories are intended for use in general dental applications by providing the dental practitioner a user interface to control operation of the dental chair and attached dental devices. The system delivers air, water, vacuum and electricity to allow the dental practitioner an intuitive control center for all common and normal patient treatment procedures performed in the dental operatory.	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.
Dentist Element	Positions	5 instrument positions	5 instruments positions	6 handpiece positions + 1 Additional
	Max. Motors	Up to 2 motors	Up to 3 motors	Up to 4 motors
	User Interface	TouchPad (No display)	Touch Pad only with buttons	EasyTouch Display 7 ", colour, plus Additional 13 keys (foil) and Status LEDs
		handsfree operation by foot control	handsfree operation by foot control	Handsfree operation with cursor control by foot control
	Syringe	3-way syringe / Sprayvit	3 way	Sprayvit M with internal heater for water and light
	Turbines	Turbines	Turbines	Turbines with light
	Motors	Motor SL (electric motor)	-	Motor BL (electric motor with light)

	Device	C8+ (K032543)	A-DEC 200 (K102234)	TENEO	
		Motor SL ISO (electric motor)	-	Motor BL ISO C (electric motor with light)	
				Motor BL implant (electric motor)	
	Control of coolant	Water amount controlled by the unit	Manual knob to open or close for water	Water amount controlled by the unit	
		Air amount controlled by the unit	Manual knob to open or close for air	Air amount controlled by the unit	
	Scaler	Sirosonic L with light	yes	Sirosonic TL with light	
	Intraoral Camera	Sirocam 3	-	Sirocam AF+	
	Curing light	Mini LED	-	Mini LED (Acteon, Satelec)	
	X-ray Viewer	X-ray viewer	X-ray image viewer	Panorama X-ray image viewer	
	Style of dentist element	Height adjustable support arm (CS, TS)	Adjustable arm with manual knob	Motor driven sliding track	
		Cart version	-	-	
		swivel arms or hanging hoses	hanging hoses	hanging hoses	
		Additional tray at dentist element	tray only on the dentist element	extra tray with an arm	
	Endodontics	-	-	Implantology functions	
		-	-	Endodontic treatment functions	
		-	-	Integrated pump for saline solution	
		-	-	Integrated Apex locator function	
	Interfaces	-	-	USB interface	
	Assistant Element	Positions	3 handpiece positions	3 handpiece positions	4 handpiece positions
		User Interface	Touch pad	Touch pad	Touch pad (foil) with 12 keys and status LEDs
		Syringe	3-way syringe / Sprayvit	3-way syringe	Sprayvit M with internal heater for water

	Device	C8+ (K032543)	A-DEC 200 (K102234)	TENEO
	Curing light	Mini LED	-	Mini LED (Acteon, Satelec)
	Suction	Suction devices	Suction devices	Suction devices
		Saliva ejector	Saliva ejector	Saliva ejector
		HVE (High volume evacuator)	HVE (High volume evacuator)	HVE (High volume evacuator)
				Surgical suction devices
	Interfaces	-	-	USB interface
		Hydrocolloid port	-	Hydrocolloid port
Chair	Patient load	Max. 135kg + 5 kg accessories	181 kg	Max. 160kg + 5 kg accessories
	Headrest	Flat headrest	Headrest	Motorized headrest
	Upholstery	Standard/lounge upholstery (sleek style)	Upholstery Care (sleek style)	Thermo upholstery / lounge upholstery (sleek style)
	Arm Rest	Arm rest	Arm rest	Arm rest removable
	Switch	Yes	-	4-way foot-switch
	Movement	Synchronized Backrest and seat movements	-	Synchronized Backrest and seat movements
		-	-	External device connection
		-	-	Massage and lumbar support function
		User programmable positions	User programmable positions	User programmable positions
		Backrest motor driven	Backrest motor driven	Backrest motor driven
		Seat motor driven	Seat motor driven	Seat and seat inclination motor driven
Water unit	Cuspidor bowl	Cuspidor bowl	Cuspidor	Motor driven cuspidor bowl
	Amalgam separator	Amalgam separator	Amalgam separator	Amalgam separator
	Water	Fresh water bottle/ Connection to municipal water	Fresh water bottle	Connection to municipal water
	Heating	Water heater	-	Water heater

	Device	C8+ (K032543)	A-DEC 200 (K102234)	TENEO
	Water / Suction hose treatment	Water treatment with continuous sanitization function	Put tablets in the water bottle	Water treatment with permanent sanitization function
		Suction hose cleaning with water	Suction hose cleaning with water	Suction hose cleaning with water
		only by flushing with water	only by flushing with water	Suction hose cleaning with chemicals
	Water treatment	Waterline Treatment solution	A-dec ICX Waterline Treatment tablets	Waterline Treatment solution
	Purge	Purge function	only by flushing with water	Purge function with auto purge
General	Operating Light	LEDview	LED light	LEDview
		Sirolux E		
	Monitor	22" monitor on the light support column	-	22" monitor on the tray incl. tray or 22" monitor on the light support frame
	Foot Control	Pneumatic Foot control available	Foot Switch	Wireless Foot control available
		Electronic foot control	Foot Control	Electronic foot control
PC Interface	-	-	Network interface	

8 PERFORMANCE DATA

The clinical assessment has been conducted for the TENEO by a dentist. TENEO's ability to fulfill the applications for which it is intended is evaluated in a critical analysis of the benefit-risk ratio by a dental practitioner.

A test concept along with the acceptance criteria have been provided. Additional information concerning system and component tests and traceability analysis has been provided.

Sterilization tests for the sterilizable TENEO components as well as for the accessories have been provided.

Biocompatibility tests for these components and accessories have also been conducted and provided.

The Sirona TENE0 Dental Treatment Unit and its accessories also comply with the following performance standards:

- ISO 7494-1 Second edition 2011-08-15 Dentistry - Dental units - Part 1: General requirements and test methods
- ISO 7494-2 First edition 2003-03-01 Dentistry - Dental units - Part 2: Water and air supply
- AAMI ANSI ISO 10993-1:2009/(R) 2013 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
- ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices
- ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 3: 2007-03 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-6 Edition 3.0 2010-01 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance -- Collateral Standard: Usability
- IEC 62304 First edition 2006-05 Medical device software - Software life-cycle processes
- IEC 62366 Edition 1.1 2014-01 Medical devices - Application of usability engineering to medical devices
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems
- ISO 14457 First Edition 2012-09-15 Dentistry - Handpieces And Motors
- ISO 7405 Second Edition 2008-12-15 Dentistry - Evaluation Of Biocompatibility Of Medical Devices Used In Dentistry [Including: Amendment 1 (2013)]
- ISO 15223-1 Second Edition 2012-07-01 Medical Devices - Symbols To Be Used With Medical Device Labels, Labeling, And Information To Be Supplied - Part 1: General Requirements
- 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 10993-10 Third Edition 2010-08-01 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

- EN 1717:2000 Protection against pollution of potable water installations and general requirements of devices to prevent pollution by backflow
- DIN 6856-3 Radiological film viewing boxes and viewing conditions - Part 3: Radiological film viewing boxes for dentistry
- ISO 6875:2011 Dental patient chair Dentistry -
- ISO 9680:2007 Operating lights Dentistry -
- ISO 11143:2008 Amalgam separators
- ISO 13485:2003 with Technical Corrigendum 1:2009 Medical devices – Quality management systems
- ISO 21530:2004 Dentistry - Materials used for dental equipment surfaces - Determination of resistance to chemical disinfectants
- IEC 80601-2-60:2012 Medical electrical equipment - Part 2-60: Particular requirements for basic safety and essential performance of dental equipment
- ISO 17664:2004 Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices
- ISO 21531:2009 Dentistry -- Graphical symbols for dental instruments

- ISO 3964 : 1982 Dental handpieces – Coupling dimensions
- DIN EN ISO 10993-5 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity Motors

9 CONCLUSION

Based on a comparison of intended use, indication, construction materials, principle of operation, features and technical data, the TENE0 Dental Treatment unit with accessories is substantially equivalent to the predicate devices.