



Food and Drug Administration
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July 17, 2015

Sirona Dental Systems GmbH
% Kofi Aninakwa
Legal Services Engineer
Sirona Dental Systems, Inc.
30-30 47th Avenue, Suite 500
Long Island City, NY 11101

Re: K150909

Trade/Device Name: Intego Family 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 17, 2015
Received: June 19, 2015

Dear Mr. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH 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

510(k) Number (if known): K150909

Device Name: INTEGO FAMILY AND ACCESSORIES

Indications for Use:

The INTEGO Family of Dental Treatment Units with accessories is intended to supply power to and serve as a base for dental devices and accessories. Each unit includes a dental chair. The units are intended for use in the dental clinic environment and are used by trained dentists and/or dental assistants.

The MOTOR BL ISO E is used to drive rotating and oscillating straight and contra-angle handpieces in connection with the dental treatment units for endodontic and general dental purposes.

The SPRAYVIT E multifunctional syringe is used for dental treatment with unheated air and unheated water. The SPRAYVIT E multifunctional syringe is also used to illuminate the preparation field.

Prescription Use X
(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)

510(k) Summary
for
Sirona Dental Systems
INTEGO FAMILY and ACCESSORIES

1 SPONSOR

Sirona Dental Systems GmbH

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64625 Bensheim

Germany

Contact Person: Kofi Aninakwa

Telephone: 718- 482 -2248

Date Prepared: July 16 2015

2 DEVICE NAME

Proprietary Names : INTEGO Family and Accessories

Common/Usual Name : Unit, Operative Dental

Classification Name : Dental operative unit and accessories.

Regulation Number : 21 CFR 872.6640

Class : 1

Product Code : EIA

Secondary Product Code : EBW

3 PREDICATE DEVICES

C8+ DENTAL OPERATIVE UNIT WITH ACCESSORIES - (K032543 - Primary Predicate)

A-DEC 200 DENTAL SYSTEM - (K102234 - Reference Predicate)

4 INTENDED USE

The INTEGO Family of Dental Treatment Units with accessories is intended to supply power to and serve as a base for dental devices and accessories. Each unit includes a dental chair. The units are intended for use in the dental clinic environment and are used by trained dentists and/or dental assistants.

The MOTOR BL ISO E is used to drive rotating and oscillating straight and contra-angle handpieces in connection with the dental treatment units for endodontic and

general dental purposes.

The SPRAYVIT E multifunctional syringe is used for dental treatment with unheated air and unheated water. The SPRAYVIT E multifunctional syringe 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. In this case the use of sterile solutions is recommended.

5 DEVICE DESCRIPTION AND FUNCTION

The INTEGO family dental treatment unit is a dental operating system. INTEGO and INTEGO pro dental treatment units constitute the INTEGO Family. These are the successors of C8+. Components and functional principles are taken over or widely derived from this C8+. The units include a patient chair, foot control, dentist element and a water unit. The units may also include an assistant element, a cuspidor a dental operating light, and a monitor.

The design concept of the INTEGO treatment unit is similar to commonly available treatment units.

The dimensions of the components, their movements and shapes are designed for ergonomic treatment; i.e. the dentist and, where applicable, the assistant can perform their treatments in a healthy working posture.

Surfaces are smooth to enable easy cleaning and disinfecting. This simplifies, in line with detachable parts and barriers as well as simple maintenance routines, efficient infection control.

The operating concept is designed to make treatments easy and intuitive to prevent mal-operations and provide an unimpeded workflow. Depending on the selected foot control and user interface version, a significant portion of functions can be operated hands-free to improve infection control and treatment workflow.

Styling and colors were selected under aesthetic aspects.

6 LEVEL OF CONCERN

The software was determined to be of a MODERATE level of concern because the software does not control a life-supporting or life-sustaining device, does not

control delivery of harmful energy, does not provide diagnostic information as a basis for treatment or therapy, and does not perform vital signs monitoring. However a latent design flaw or malfunction of the system software, though improbable, would result in minor injury to the patient or operator. Software documents consistent with the requirements for MODERATE level of concern software, as specified in FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, were provided.

7 TECHNOLOGICAL CHARACTERISTICS SUMMARY

The INTEGO Family and Accessories has similar physical and technical characteristics to the predicate devices, as illustrated in the table below. As shown in the substantial equivalence table below, there are only minor differences between the proposed and predicate devices and nothing significant that would render the device non-substantially equivalent. The entire Indications for use for the Intego Family and Accessories include language for the MOTOR BL ISO E and SPRAYVIT E. These accessories have been tested and comply with applicable recognized consensus standards and are comparable to FDA cleared counterparts. As such the overall differences between the indications for use of the INTEGO Family and Accessories and predicate C8+ do not affect the safety and effectiveness of the INTEGO Family and Accessories.

	Device	C8+ (K032543)	A-DEC 200 (K102234)	INTEGO Family
	Intended Use	The CS+ 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.	The INTEGO Family of Dental Operative Units with accessories is intended to supply power to and serve as a base for dental devices and accessories. Each unit includes a dental chair. The units are intended for use in the dental clinic environment and are used by trained dentists and/or dental assistants.
Dentist Element	Positions	5 instrument positions	5 instruments positions	5 instrument positions + 1 Additional
	Max. Motors	Up to 2 motors	Up to 3 motors	Up to 2 drill drives
	User Interface	TouchPad (No display)	Touch Pad only with buttons	Touchpad (EasyPad) with 7-segment display
				Touch display (EasyTouch) Display

	Device	C8+ (K032543)	A-DEC 200 (K102234)	INTEGO Family
				4.3" (optional)
		handsfree operation by foot control	handsfree operation by foot control	Handsfree operation with cursor control (with EasyTouch)
	Syringe	3-way syringe / Sprayvit	3 way	3 way syringe / Sprayvit E with light
	Turbines	Turbines	Turbines	Turbines with light
	Motors	Motor SL (electric motor)	.	Motor BL ISO E (electric motor with light)
		Motor SL ISO (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 L with light
	Intraoral Camera	Sirocam 3	.	Sirocam F / Sirocam AF
	Curing light	Mini LED (Acteon Satelec)	.	Mini LED (Acteon, Satelec)
	X-ray Viewer	X-ray viewer	X-ray image viewer	X-ray image viewer
	Style of dentist element	Height adjustable support arm (CS, TS)	Adjustable arm with manual knob	Height adjustable support arm with pneumatic brake
		Cart version	.	
		swivel arms or hanging hoses	hanging hoses	swivel arms or hanging hoses (CS / TS)
		Additional tray	tray only on the	Additional tray at dentist element

	Device	C8+ (K032543)	A-DEC 200 (K102234)	INTEGO Family
		at dentist element	dentist element	
	Endodontics	.	.	Torque control kit
	Interfaces	.	.	USB interface
Assistant Element	Positions	3 handpiece positions	3 handpiece positions	4 handpiece positions
	User Interface	Touch pad	Touch pad	Touch pad
	Syringe	3-way syringe / Sprayvit	3-way syringe	3 way syringe / Sprayvit E with light
	Curing light	Mini LED (Acteon Satelec)	.	Mini LED
	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)
	Interfaces	.	.	USB interface
		Hydrocolloid port	.	Hydrocolloid port
	Chair	Patient load	Max. 135kg + 5 kg accessories	181 kg
Headrest		Flat headrest	double-articulating headrest	Flat headrest
		Articulating headrest	.	Double articulated headrest
Upholstery		Standard/lounge upholstery (sleek style)	Upholstery Care (sleek style)	Thermo upholstery (sleek style)
Arm Rest		Arm rest	Arm rest	Arm rest
Switch		4-way foot-switch	.	4-way foot-switch

	Device	C8+ (K032543)	A-DEC 200 (K102234)	INTEGO Family
	Movement	Synchronized Backrest and seat movements	.	Synchronized Backrest and seat movements
		.	.	External device connection
		.	.	Pressure reduction kit
		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 motor driven
Water unit	Cuspidor bowl	Cuspidor bowl	Cuspidor	Cuspidor bowl
	Amalgam separator	Amalgam separator	Amalgam separator	Amalgam separator
	Water	Fresh water bottle/ Connection to municipal water	Fresh water bottle	Fresh water bottle / Connection to municipal water
	Heating	Water heater	.	Water heater
	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	Dentosept P Waterline Treatment	A-dec ICX Waterline Treatment tablets	Dentosept P Waterline Treatment solution

	Device	C8+ (K032543)	A-DEC 200 (K102234)	INTEGO Family
		solution		
	Purge	Purge function	only by flushing with water	Purge function with auto purge
General	Operating Light	LEDview	LED light	LEDview
		Sirolux E		LEDlight
	Monitor	22" monitor on the light support column	.	22" monitor (with integrated power supply) on light support column
	Foot Control	Pneumatic Foot control available	Foot Switch	Pneumatic Foot control available
		Electronic foot control	Foot Control	Electronic foot control
	PC Interface	.	.	Network interface

8 NON CLINICAL TESTING

An evaluation using relevant literature and a critical appraisal of the Dental Treatment Unit and accessories by a medical professional have been performed. Sirona's motors pass applicable recognized consensus standards for product code EBW. FDA cleared standalone motors also pass these applicable consensus standards. As such Sirona's motors are comparable to their standalone counterparts. The Sirona INTEGO Family and 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
- ISO 9680:2007 Dentistry - Operating lights
- ISO 11143:2008 Dentistry - 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 Sirona INTEGO family is as safe and as effective to perform its intended use and is substantially equivalent to the predicate devices.