DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 10, 2017

Dentsply Sirona
Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60
York, Pennsylvania 17404

Re: K161213
Trade/Device Name: XSmart iQ
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EBW
Dated: January 13, 2017
Received: January 17, 2017

Dear Helen Lewis:

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,

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)*

K161213

Device Name
XSmart iQ

Indications for Use *(Describe)*
XSmart iQ is a cordless motor hand-piece with torque control used for driving files in both reciprocating and continuous mode during an endodontic procedure.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K161213

510(k) SUMMARY

Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343
Email Address: helen.lewis@dentsplysirona.com

Date Prepared: February 9, 2017

Device Name:

- Proprietary Name: XSmart iQ
- Classification Name: Dental hand-piece and accessories
- CFR Number: 872.4200
- Device Class: II
- Product Code: EBW

Predicate Device:

Predicate Device Name	510(k)	Company Name
e3 Torque Control Motor	K103653	Dentsply Sirona

Description of Device:

The XSmart iQ is a cordless motor hand-piece having a power stage (motor hand-piece, gears and power supplier), a console based on an Apple iPad Mini® and a communication system (Bluetooth). The motor parameters can be transferred, stored and displayed via a dedicated iPad Mini® application (Endo iQ app), connected to the cordless motor hand-piece through a Bluetooth communication protocol.

Device components (including accessories):

- Motor hand-piece support and case
- Motor hand-piece
- Contra angle
- Spray nozzle (used for lubrication)
- iPad Mini® Protective case (Rubber Plugs and Protective case opener)
- AC adapter
- Getting started guide
- iPad Mini® with Endo iQ iOS App (not part of the kit)

The contra angle is an attachment to motor hand-piece and is physically manufactured by W&H. The contra angle is specific to XSmart iQ motor hand-piece. The contra angle is designed to transmit the rotational movement of the motor axle to the shank of a bur or file that will be inserted into the output end of the contra angle. The output end of the contra angle contains chuck systems to accommodate standardized bur and file shanks. The contra angle is compatible with rotary and reciprocating files, with a 2.35 mm shaft conforming to ISO 1797-1:2011, Type 1.The contra angle is designed to be used for driving files in both reciprocating and continuous rotation mode during an endodontic procedure.

Indications for Use:
XSmart iQ is a cordless motor hand-piece with torque control used for driving files in both reciprocating and continuous rotation mode during an endodontic procedure.

Substantial Equivalence:
Technological similarities and differences are as follows:

Table 5.1 Comparison between e3 Torque Control Motor (K103653) and XSmart iQ

No	**Feature**	**Predicate Device** e3 Torque Control Motor K103653	**Proposed Device** XSmart iQ (K161213)	**Similarities/Differences**
1	Indication for Use	The e3 Torque Control Motor (K103653) is a medical device designed for use by dentists for use with dental root canal instruments in continuous rotation with torque control or in reciprocating movement.	XSmart iQ is a cordless motor hand-piece with torque control used for driving files in both reciprocating and continuous rotation mode during an endodontic procedure.	No differences.
2	Features	Corded motor hand-piece	Cordless motor hand-piece	
		Continuous rotation and reciprocating movement	Continuous rotation and reciprocating movement	No differences.
		Can be controlled by LED console or foot pedal	The motor parameters can be transferred, stored and displayed via an Apple iPad Mini® application (Endo iQ app), via Bluetooth connection and controlled by the push button on the motor hand-piece.	XSmart iQ motor hand-piece is controlled by push button on the motor hand-piece, while e3 Torque Control Motor is controlled by LED console and foot pedal.
		USB connection for software updates	Bluetooth connection for software updates	XSmart iQ uses Bluetooth to connect with iPad Mini® and to update the firmware while e3 Torque Control Motor uses USB port to update the firmware.

Table 5.1 Comparison between e3 Torque Control Motor (K103653) and XSmart iQ				
No	**Feature**	**Predicate Device** e3 Torque Control Motor K103653	**Proposed Device** XSmart iQ (K161213)	**Similarities/Differences**
		The torque control feature prevents the rotary file from exceeding required torque strength	The torque control feature prevents the rotary file from exceeding required torque strength	No differences.
3	Console	LED console display with membrane keypad	iPad Mini® display with iPad Mini® application (Endo iQ app)	iPad Mini® application gives interactive information (real time graphs, images) and access to pre- and post-operation information.
		LED screen for visual selection of preprogrammed setting or for preforming customized settings	iPad Mini® application (Endo iQ app) with pre-defined torque and speed settings.	
		Control unit has keypad interface for selection of desired functions which are as follows: 1. To switch device on (LED on) and off (LED off). 2. To show battery status; 3. To scroll right/left in the bottom row of the display through the file system, file, torque and speed fields. Also used for navigation of menu functions.	A user management that can be used for following: 1. To edit user profile 2. To log out and change user 3. statistics about application 4. Pop-up menu that contains parameter, statistics 5. Record treatment with treatment notes 6. Treatment reports allows user to: • Create, edit or delete a patient. • View, edit or delete the treatments associated with the patients	
4	Safety Mechanisms	The e3 Torque Control Motor has safety mechanisms for preventing the file being over-torqued while in operation by implementing a torque control feature that will reverse the direction of the file if the torque exceeds a predefined limit.	XSmart iQ has safety mechanisms for preventing the file being over-torqued while in operation by implementing a torque control feature that will reverse the direction of the file if the torque exceeds a predefined limit	No differences.
5	Manufacturer	Dentsply Sirona /ATR	Dentsply Sirona /ATR/W&H	No differences.

Table 5.1 Comparison between e3 Torque Control Motor (K103653) and XSmart iQ				
No	**Feature**	**Predicate Device** e3 Torque Control Motor K103653	**Proposed Device** XSmart iQ (K161213)	**Similarities/Differences**
6	Dimensions	203.2 mm X 76.2mm X 76.2mm	206 mm X 24.6 mm X 24.8 mm	It facilitates the motor hand-piece maneuverability in tight spaces
Composition of Materials				
7	Materials of Motor Hand-Piece	PC /ABS blend PC-Polycarbonate ABS- Acrylonitrile butadiene Styrene	PBT/PET blend (polybutylene terephthalate/ polyethylene terephthalate) stainless steel 316L silicone	Materials of XSmart iQ motor hand-Piece are more resistant to high-level disinfectant solutions.
Technical Specifications				
8	Type of Chuck	Push button	Push button	No differences.
9	Coupling Dimensions	2.35 mm, according to ISO 1797-1/-2	2.35 mm, according to ISO 1797-1/-2	No differences.
10	Types of Connectors	ISO 1797-1/-2	ISO 1797-1/-2	No differences.
11	Lubricant Delivery System	Spray nozzle	Spray nozzle	No differences.
12	Shank Length	ISO 1797-1/-2, latching	ISO 1797-1/-2, latching	No differences.
13	Reduction Rate	6:1	6:1	No differences.
14	Weight	About 2 pounds(including LED console)	About 0.4 pounds	XSmart iQ motor hand-piece is lighter in weight as compared to e3 Torque Control Motor.
15	Power Supply	Recyko Ni-MH 6 Volt rechargeable battery	Lithium ion battery: 3.6V , 2000 mAh	Lithium ion batteries of XSmart iQ are of higher capacities and relatively low self-discharge with low maintenance.
16	Battery Indicator	E3 Torque Control Motor has three different color LED lights to display battery charging status: 1. Green: Battery has sufficient capacity 2. Flashing red: Battery needs to be charged and the device can operate on battery power for only a few minutes. Before the	Motor hand-piece battery level is displayed on iPad Mini® application. The motor hand-piece of XSmart iQ has two different color LED lights with sound which will inform user about the status of the battery. 1. All LEDs off- The battery is completely flat 2. Green LED light- Battery is completely	e3 Torque Control Motor has Flashing orange LED light when battery is charging while XSmart iQ motor hand-piece has green LED light when charging. Also XSmart iQ has different audible signals as compared to e3 Torque Control Motor which make user aware about different battery situations.

Table 5.1 Comparison between e3 Torque Control Motor (K103653) and XSmart iQ				
No	**Feature**	**Predicate Device** e3 Torque Control Motor K103653	**Proposed Device** XSmart iQ (K161213)	**Similarities/Differences**
		motor switches off, there is an audible warning signal 3. Flashing orange: The orange LED shows that the battery is charging.	charged or enough battery available to complete the treatment. 3. Red LED light and audible signal with one short beep- battery charge level is low. 4. Red LED light with three-second beep- battery charge level is critical.	
17	Charger Power Supply	AC 100-240 Volts	AC 100-240 Volts	No differences.
18	Frequency of Supply Voltage	47-63 Hz	50-60 Hz	XSmart iQ motor hand-piece operates at a narrow frequency range of supply voltage while e3 Torque Control Motor hand-piece operates at broad frequency range of supply voltage.
19	Torque Range	20-410 gram-cm	50-510 gram-cm	More torque of the XSmart iQ motor hand-piece gives more energy/power during endodontic treatment as compared to e3 Torque Control Motor.
20	Speed Range of the Micro Motor Shaft	250-1000 RPM (in rotary mode)	1200 - 5100 RPM (in rotary mode)	More speed of XSmart iQ motor hand-piece produces more power which delivers constant torque.
21	Operating Mode	Rotary and reciprocating	Rotary and reciprocating	No differences.
22	Transport and Storing Conditions:	Ambient temperature: -20°C - +50°C (-4°F - 122°F) Relative humidity : 20-90%	Ambient temperature: -20°C - +50°C (-4°F - 122°F) Relative humidity: 20% - 80%	No differences.
23	Bluetooth	No Bluetooth	Bluetooth 4.0 low energy	Bluetooth is a communication mean for XSmart iQ motor hand-piece to connect with iPad Mini® and update

Table 5.1 Comparison between e3 Torque Control Motor (K103653) and XSmart iQ				
No	**Feature**	**Predicate Device** e3 Torque Control Motor K103653	**Proposed Device** XSmart iQ (K161213)	**Similarities/Differences**
				firmware on motor hand-piece.
24	Micro Motor	Brushless	Brushless	No differences.
25	Speed and Torque Adjustable	40 Torque Settings, 75 speed steps	50 Torque setting 60 speed steps	More speed and torque settings of XSmart iQ gives more options
26	Own Settings Can Be Saved	Yes	Yes	No differences.
27	Auto Stop Reverse	Yes	Yes	No differences.
28	Reverse Signal	Yes	Yes	No differences.
29	Torque Warning Signal	Yes	Yes	No differences.
30	USB port	Yes	No	Bluetooth is used to update firmware on the XSmart iQ motor hand-piece.
31	Motor Operation by Push Button on Motor Hand-Piece	No	Yes	Push button on the motor hand-piece helps clinicians to control the device during endodontic treatment.
32	Motor Operation by Foot Pedal	Optional	No	XSmart iQ motor hand-piece is controlled by a push button on the hand-piece while e3 Torque Control Motor is controlled by the foot pedal and LED console.
33	System Performance with Time Stamp	No	Yes	Time stamps give the user ability to identify actual event time or endodontic treatment time.
Contra Angle/Attachment				
34	Contra Angle/ Attachment	6:1 contra angle cleared by FDA under K972436 (Product Code: EFB)	W& H contra angle specific (exclusive) to XSmart iQ	The design and materials of XSmart iQ contra angle are the same as the contra angle sold with the e3 Torque Control Motor. However, the XSmart iQ contra angle can only be used with XSmart iQ motor hand-piece.
35	Primary Contra Angle	6:1	6:1	No differences.

Table 5.1 Comparison between e3 Torque Control Motor (K103653) and XSmart iQ				
No	**Feature**	**Predicate Device** e3 Torque Control Motor K103653	**Proposed Device** XSmart iQ (K161213)	**Similarities/Differences**
	Gear Ratio			
Lubricant				
37	Lubricant	W&H Service Oil F1 (K010127)	W&H Service Oil F1 MD-400 Oil spray can, 400 ml. (K010127)	No differences.

The differences between the proposed device and the predicate device as shown in in Table 5.1 do not affect substantial equivalence. The underlying performance of the proposed device remains unchanged with the addition of an iPad interface and the speed and torque change remains within endodontic treatment parameters as summarized in the Non-Clinical Performance Data section, Table 5.4.

Summary of Non-Clinical Performance Data

Biocompatibility: Cytotoxicity was performed on all patient contacting materials including contra angle in accordance with ISO 10993-5:2009, EN ISO 10993-1:2009 and ISO 7405:2008-Dentistry - Evaluation of biocompatibility of medical devices used in dentistry. All patient contact components demonstrated biocompatibility.

Table 5.2 Biocompatibility testing standards and results for XSmart iQ contra angle		
No	**Biocompatibility Testing:**	**Results**
1	EN ISO 10993-1:2009 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	Test results indicated that the XSmart iQ contra angle complies with the applicable Standard.
2	EN ISO 10993-5:2009-Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Test results indicated that the XSmart iQ contra angle complies with the applicable Standard.
3	ISO 7405:2008-Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.	Test results indicated that the XSmart iQ contra angle complies with the applicable Standard.
4	DIN EN ISO 10993-5, 1999 Biological evaluation of medical devices Part 5: tests for cytotoxicity	Test results indicated that the XSmart iQ contra angle complies with the applicable Standard.

Electromagnetic compatibility and electrical safety: The following Electrical safety and electromagnetic compatibility (EMC) testing were performed on the XSmart iQ to verify conformity to standards and demonstrate substantial equivalence to the predicate e3 Toque Control Motor (K103653).

Table 5.3 Electromagnetic compatibility and electrical safety testing for XSmart iQ		
No	**Standards**	**Results**
1	IEC 60601-1:2005/A1:2012 (3rd Ed.) Medical electrical equipment —Part 1: General requirements for basic safety and essential performance	Test results indicated that the XSmart iQ complies with the applicable Standard.
2	IEC 80601-2-60:2012 Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment.	Test results indicated that the XSmart iQ complies with the applicable Standard.
4	EN 60601-1-2:2007 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance— Collateral standard: Electromagnetic compatibility — Requirements and tests	Test results indicated that the XSmart iQ complies with the applicable Standard.
5	EN 60601-1-6:2010-Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance.	Test results indicated that the XSmart iQ complies with the applicable Standard.
6	IEC 60601-1-8:2012 Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.	Test results indicated that the XSmart iQ complies with the applicable Standard.

Performance testing was performed in accordance to international standards DIN EN ISO 14457-2012 Dentistry–Hand-pieces and motors and demonstrates substantial equivalence to the predicate e3 Toque Control Motor (K103653). The following testing were conducted to demonstrate the basic performance of the XSmart iQ and its accessories and confirmed that the XSmart iQ performs as intended.

Table 5.4 Performance Test for XSmart iQ and Accessories			
No	**Test**	**Method**	**Results**
1	Expected Life	Testing was conducted to evaluate the expected life of the micro motor, contra angle. Test included contra angle connection test, the impact on electronics and entire device and contra angle play measurement. Testing was conducted to evaluate battery capacity. All endurance tests were conducted with sample size of n=15 for the first pass and n=5 for the second pass.	XSmart iQ passed the test.
2	Micro-Motor Performance Test	Motor performance testing was completed utilizing a Magtrol test bench at: 850 rpm rotary, motor torque set at maximum, with driven torque ramp, and then subsequently with no load	The device withstood load (at least until 16 milli-Newton meters) with a failure rate of 0% and no impact or motor defects observed after a 500 hours of runtime
3	Motor Hand-Piece and Contra Angle Endurance Test	Endurance testing for the motor hand-piece and contra angle were conducted utilizing an oil-break test bench at 500 hours (equivalent to 5 years operation); 1,600 contra angle application/removal cycles. (Equivalent to 100% of 3 year expected life as worst case); and 25 contra angle lubrication cycles.	Endurance testing passed successfully and no major impact from stress is expected in the lifetime of device.
4	Contra Angle Connection Test	Endurance testing for the contra angle was conducted parallel to the micro-motor and contra angle test with 1,600 contra angle application/removal cycles. (Equivalent to 100% of 3 year expected life as worst case); 500 hours of runtime and 25 contra angle lubrication cycles.	Endurance testing passed successfully and no major impact on the expected lifetime of device is expected through stress
5	Battery Capacity Evaluation	Battery was fully charged and the motor hand-piece was then completely discharged by disconnecting the charger and measuring discharge time while running on an oil-break test bench with torque of 2 mNm (milli-Newton meters) at 2 minutes reciprocating and a 1 minute pause to calculate the capacity of the battery.	Battery capacity showed minor changes after 500 hours of runtime and approximately 300 charge cycles. No degradation of the cells was observed and the test was passed successfully.
6	Oil-Ingress into Motor Test	Oil ingress can be detected by significant change of micro-motor performance and inability to calibrate contra angle successfully.	After 750 hours of runtime and 25 contra angle lubrication cycles no ingress of oil could be observed. This test was passed successfully.
7	Performance Tests Motor Hand-Piece	The battery is fully charged and contra angle is lubricated prior to testings. During the test, device is not connected to main power. The output and performance of device is expressed by the movement of file. Following four parameters were reviewed: speed torque and reciprocating movement. In addition warning beeps indicating performance limits were examined.	XSmart iQ motors undergoing performance test passed the defined examination. No device failure occurred during test phase.

Table 5.4 Performance Test for XSmart iQ and Accessories			
No	**Test**	**Method**	**Results**
8	Apex Pass Through	Proof of functionality test: To test functionality and length measurement accuracy with external apex locators. A multimeter is used to measure the electrical resistance. To determine the resistance of the pass through the file and the apex output contacted. To measure the isolation of contra angle the contra angle and housing parts are contacted. The capacity measured through LCR meter. Display readings of two external apex locators were measured.	Test has shown the resistance the housing isolation and capacity requirements are met by XSmart iQ. Also the display locations of two apex locators are not influence by measurement through XSmart iQ internal contact.
9	Blue Tooth Simultaneous Connection Test	To test the Bluetooth functionality of XSmart iQ. The motor hand-piece and iPad Mini® were paired one at a time. After pairing, normal use was simulated.	No interference between the devices was observed.
10	Marking Tests	Markings on XSmart iQ were rubbed by hand, first for 15 seconds with cloth soaked in distilled water then with ethanol then with isopropyl alcohol. And pictures were taken after each marking.	No degradation in the readability of marking was observed.
11	Endurance Battery Test	To evaluate the performance of batteries used in the XSmart iQ. 300 charging /discharging cycles- charge battery until the battery voltage reached 4.14V and then discharge battery with 1000mA. The time to discharge was recorded. And then inner resistance was calculated.	All test passed. No major impact of charging/discharging on lifetime and function of batteries.
12	Button Test	To evaluate performance of the system buttons on XSmart iQ. Test robot pushing button (1) and button (2).Test person performs visual inspection after 10,000, 38,000 and 50,000 push cycles.	All buttons were functional after applying the defined push cycles.
13	Alarm Test	To verify that XSmart iQ motor hand-piece fulfills the IEC 60601-1-8:2012 "General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems" in regard to alarm tones.	XSmart iQ passed the alarm test.
14	Contra Angle Tests	Test was performed on the contra angle head as per ISO 14457:2012. Following tests were performed: 1. Measurement of the backlash 2. Lifespan test with VDW drive 3. Sterilization resistance test in Nitram DAC Universal 4. Thermodisinfectability test in Miele G7835CD	The backlash fluctuated within the stipulated tolerance of ±6°. The contact quality when transferring the signal on the sliding contact was good at all times and remained within the stipulated range, above 895, on the VDW Gold drive unit. The resistance value remained below 5 ohms at all time (below 15 ohms required). The sterilization did not reveal any decisive negative influences that would affect the use of the test objects in practice.

Table 5.4 Performance Test for XSmart iQ and Accessories			
No	**Test**	**Method**	**Results**
			The thermo washer disinfection does not affect the usability of the contra angle heads. There were no incidents during the test affecting use to an extent that would raise concerns about releasing the product.
15	Effectiveness of Contra Angle Test	To determine the effectiveness of the XSmart iQ endodontic contra angle head and determine the ultimate moment of the endodontic contra angle head Efficiency: The cut-out torques were determined on the KSM performance test bench at 300 rpm with different settings (10%, 20%, 30% etc.) and backed up statistically (10 values for each setting). Ultimate moment: This is measured on the KSM performance test bench (ID no: 582.0000), axis 2. Here, the axis is set to 2 Nm in manual mode, i.e. virtually blocked. The contra angle head is then powered manually until something breaks. The torque is recorded over the entire period.	The efficiency levels measured (90%–95%) are significantly over the 80% required. The test measured the two prototype instruments without a serial number that were also used to measure the efficiency. At 66 and 70 Ncm (Newton Centimeter), the ultimate moments fell within the same range on the drive side.
16	Dimensional Benchmark	The aim of this test was to compare various dimensional specifications of the hand- piece and contra angle of the XSmart iQ motor compared to other competitor cordless endo-motors. The docking station heights and footprints were measured.	The maximum diameter of the complete IQ hand- piece was the smallest of the cordless benchmark and XSmart iQ passed the dimensional benchmark test as per test criteria.
17	Docking Station Disinfection Test	The aim of this test was to test if all the pieces of the docking station resist to disinfection with several solutions. The tests were made as described in the ISO 21530 standard.	Docking station passed the test after 250 spraying cycles according to ISO 21530 standard.
18	Resistance to Closing Opening Cycle Test	The aim of this test was to test if all the pieces of the docking station resist to several closing-opening cycles corresponding to a normal usage during 2 years.	XSmart iQ docking station will not suffer any wear problems during two year usage.
19	Bluetooth Working Distance	The aim of this test was to measure the working distance of the Bluetooth connection between the XSmart iQ motor hand-piece and its docking station.	XSmart iQ passed Bluetooth working distance test as per test criteria.
20	Packaging Resistance Test	The aim of this validation was to control if the docking station and the X-Smart IQ packaging would resist to hard conditions, like drops, crashes, high loads, vibrations and high temperatures and humidity.	No visible cracks, color change and deformation on docking station. No mechanical damage visible and no

Table 5.4 Performance Test for XSmart iQ and Accessories			
No	**Test**	**Method**	**Results**
			electrical damage detected on the devices contained in the packaging, after the transportation test and the climatic conditioning.
21	Usability Test	To verify or validate the usability requirements (usability engineering) according to IEC 62366:2007 on XSmart iQ	Test results indicated that the XSmart iQ complies with the applicable Standard.

Software validation:

Both devices meet software validation requirement per EN 62304:2006.

The performance of the XSmart iQ satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence. Along with the above tests, sterilization validation, speed and torque accuracy testing, and motor hand-piece endurance tests were also conducted. All testing demonstrated compliance with requirements of the standards and there are no safety hazards.

Human Factors:

All established Human Factors test requirements were met as developed from the FDA Guidance, *Applying Human Factors and Usability Engineering to Medical Devices.* All participants in the user evaluation exhibited efficiency with no significant residual use related risk remaining after testing.

Clinical Performance Data

Not applicable.

Risk analysis method & actions:

A Risk Management Plan to identify the risks and activities for managing those risks was carried out during design and development of the XSmart iQ motor hand-pieces and accessories. The risk analysis of the XSmart iQ was conducted in accordance with ISO 14971: 2012.

Table 5.5 Risk identification and mitigation for XSmart iQ		
No	**Identified Risk**	**Mitigation Measure**
1	Cross contamination and adverse tissue reaction	Single use barrier covers for the iPad Mini® and motor hand-piece should be used to minimize the risk of cross contamination. The main risks arise from cross-contamination or lack of biocompatibility. Reprocessing has been validated. The DFU section on sterilization was carefully written in order to comply with applicable standards and best practices. All materials used are well-known and tested in other contra angles in order to minimize the risk of biocompatibility issues
2	Device malfunction	Testing was conducted to minimize the risk of loss of function due to corrosion or wear and tear.
3	Risks arising due to the use of a battery (electrical injury)	A number of risks arise from the use of a lithium-ion battery cell. Overcharge, overcurrent or excessive environmental temperatures could lead to spontaneous fire. Torque control, an appropriate charge circuitry, use of a medical (IEC 60601-1 compliant) charge adapter and training procedures and work instructions mitigate these risk. The battery is tested to comply with IEC 62133. An empty battery can also pose a risk. The user interface (LEDs, warning tones) has been designed in such a way as to inform the user in time so that a treatment can be completed before the device runs out of energy. Finally, batteries can leak toxic fluid. The user is instructed on how to handle this problem in the directions for use (DFU).
4	Risk arising due to transfer of energy (Thermal Injury and electromagnetic interference)	Heat, mechanical energy (vibrations), electromagnetic energy (EMC), noise has been considered. The motor control was designed to minimize vibrations. Heat dissipation was measured and shown to be below the limits required by IEC 60601-1. Overall, no significant risks arise in this category.
5	Risks arising on behalf of user error, usability or foreseeable misuse (improper use and maintenance)	The user interface was designed and carefully validated with a goal of reducing complexity. Normed symbols were used, wherever possible. In the control unit, symbols and text were used together in order to minimize the risk of mis-understanding. Great care was taken to distinguish reciprocating and rotary operating modes. The understand-ability of symbols and labelling was validated in a user evaluation. Oil ingress into the micro motor is a known problem from previous products. The support stand was designed in a way to minimize this problem. A proprietary connector was used for the apex locator and charge adapter contact in order to prevent the user from using other charge adaptors: a misuse which can potentially expose the patient to the risk of electric shock. The charge connector over-molding was designed in a way to prevent wrong insertion. Likewise, a proprietary coupling was used for the contra angle and designed in such a way that third-party contra angles will not couple. This will prevent users from using a contra angle with a different reduction ratio, resulting in wrong speed/torque threshold at the file.
6	Risks arising due to wireless communication	The standard risks arising from using wireless communication are considered (loss of data. corrupted data, inappropriate timing, unexpected receipt of data, etc.). A communication protocol between the motor hand-piece and control unit has been designed to deal with these risks. The protocol has been tested extensively, using automated, model-based tests.
7	Risks arising due to the use of the contra angle	In general, the risk arising from the use of a contra angle in endodontic applications is lower than for high-speed applications: the speed range considered is from 250rpm to 850rpm. Transfer of heat, noise, or vibrations to patient or operator have been considered.

Conclusion Regarding Substantial Equivalence

The cordless motor hand-piece allows the customer to experience the functionality of e3 Toque Control Motor (K103653) without any wires attached. XSmart iQ has Bluetooth for software updates while the e3 Toque Control Motor (K103653) has a USB port for software updates. XSmart iQ has more torque than e3 Toque Control Motor (K103653) which makes it well suited for endodontic procedures. The updated speed range and torque range is compatible with all Dentsply Sirona file products sold in North America which also helps in endodontic techniques. XSmart iQ contra angle compares favorably with the e3 Toque Control Motor (K103653) in terms of compactness.

Test data to verify the performance of the XSmart iQ has been provided including: biocompatibility, electrical safety, electromagnetic compatibility and non-clinical performance testing for both hardware and software functions and the results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.