May 18, 2023

Foshan COXO Medical Instrument Co., Ltd.
% Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
CHINA

Re: K220829
Trade/Device Name: Endo Motor
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX, LQY
Dated: April 24, 2023
Received: April 24, 2023

Dear Ray Wang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael E. Adjodha -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220829

Device Name
Endo Motor

Indications for Use *(Describe)*
C-SMART-I PRO, C-SMART-I PILOT, C-SMART-MINI AP:
The Endo Motor device is an endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.
C-Smart-mini:
The Endo Motor device is an endodontic treatment motorized handpiece. It can be used to enlarge canals. It can be used as a low-speed motorized handpiece. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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The assigned 510(k) Number: K220829

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation:2023/05/17

2. Sponsor Identification

Foshan COXO Medical Instrument Co., Ltd.
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3. Designated Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Endo Motor
Common Name: endodontic treatment motorized handpiece/root canal apex locator

Regulatory Information
Classification Name: Handpiece, Direct Drive, Ac-Powered
Classification: 1
Primary Product Code: EKX
Regulation Number: 872.4200
Secondary Product Code: LQY
Review Panel: Dental

Indication for use Statement:

C-SMART-I PRO, C-SMART-I PILOT, C-SMART-MINI AP:
The Endo Motor device is an endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

C-Smart-mini:
The Endo Motor device is an endodontic treatment motorized handpiece. It can be used to enlarge canals. It can be used as a low-speed motorized handpiece. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

Device Description:

C-SMART-I PRO
The Endo Motor device C-SMART-I PRO is a low-speed rotating oral equipment mainly used for root canal preparation and root canal measurement. The product is a portable device powered by built-in lithium batteries and charged by the adapter. LCD displays parameters such as speed, torque, working mode, apex position, etc. Users can also set and modify by keys, and provide design of factory initialization, calibration and functional check of the apex locator.

The Endo Motor device is an endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

The Endo Motor device C-SMART-I PRO is intended to be sterilized prior to use.

The material composition of root canal files that can be used with the Endo Motor device C-SMART-I PRO is Nickel titanium (NiTi). These files are not included in the submission.

There are three working modes as:
M1: Apex locator only.

M2: Motor only.

M3: (Dual mode) Motor with apex location function.

C-SMART-I PILOT

The Endo Motor device C-SMART-I PILOT is a low-speed rotating oral equipment mainly used for root canal preparation and root canal measurement. The product is a portable device powered by built-in lithium batteries and charged by the adapter. LCD displays parameters such as speed, torque, working mode, apex position, etc. Users can also set and modify by keys, and provide design of function check, calibration, factory reset and can connect handpiece to control unit via Bluetooth.

The Endo Motor device is an endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

The Endo Motor device C-SMART-I PILOT is intended to be sterilized prior to use.

The material composition of root canal files that can be used with the Endo Motor device C-SMART-I PILOT is Nickel titanium (NiTi). These files are not included in the submission.

There are three working modes as:
Endo motor mode: root canal preparation.
Apex locator mode: root canal length measurement.
Multi-function mode: undertake root canal measurement and preparation.

C-SMART-MINI AP

The Endo Moto device C-SMART-MINI AP is a low-speed rotating oral equipment mainly used for root canal preparation and root canal measurement. The product is a portable device powered by built-in lithium batteries and charged by the adapter. LCD displays parameters such as speed, torque, apex position, etc. Users can also set and modify by keys, and provide design of functional check, calibration, set dominant hand and factory reset.

The Endo Motor device is an endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

The Endo Motor device C-SMART-MINI AP is intended to be sterilized prior to use.

The material composition of root canal files that can be used with the Endo Motor device C-SMART-MINI AP is Nickel titanium (NiTi). These files are not included in the submission.

There are three working modes as:

Endo motor: Prepare the root canal, without apex locator function.
Apex Locator: Measure the length of the root canal, without motor function.
Multi-function: Measuring the length while root canal preparation.

C-Smart-mini

The Endo Motors device C-Smart-mini is a low-speed rotating oral equipment mainly used for root canal preparation. The product is a portable device powered by built-in lithium batteries and charged by the adapter. LCD displays parameters such as speed, torque, rotary files program, etc. Users can also set and modify by keys, and provide design of calibration and screen display for right- or left-handed user.

The Endo Motor device is an endodontic treatment motorized handpiece. It can be used to enlarge the canals. It can be used as a low-speed motorized handpiece. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

The Endo Motor device C-Smart-mini is intended to be sterilized prior to use.

The material composition of root canal files that can be used with the Endo Motor device C-Smart-mini is Nickel titanium (NiTi). These files are not included in the submission.

5. Identification of Predicate Device(s)

Predicate Device
K201993
E-connect S Endo Motor with built-in Apex Locator
Changzhou Sifary Medical Technology Co., Ltd.

Reference Device:
510(k) Number: K161213
Product Name: XSmart iQ
Manufacturer: Dentsply Sirona

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.

- ISO 10993-23 First edition 2021-01Biological evaluation of medical devices - Part 23: Tests for irritation
- IEC 60601-1:2012, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment;
- ISO 14457:2017 Dentistry - Handpieces and motors;
- IEC 62133 Edition 2.0 2012-12 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications;
- IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- ISO 14457 Second edition 2017-10 Dentistry - Handpieces and motors
- FCC 47 CFR, Part 15, Subpart C, Section 15.247, 15.207 &15.209
- AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems.
- IEC 62304:2015 Medical device software - Software life cycle processes.
- IEC 62366-1:2020 Medical devices - Part 1: Application of usability engineering to medical devices.
- Bluetooth and Wireless Charging testing.
- Accuracy Testing (Internal test methods to demonstrate the apex position measurement accuracy of ±0.5mm).
- Software documentation for a moderate level of concern per FDA Guidance Document: “Guidance for the Content of Premarket Submissions for Software Contained in Medical Device”.
- Cleaning, Disinfection and Sterilization validation for components of the proposed device according to the FDA Guidance Document: “Reprocessing Medical Devices in Health Care Setting: Validation Methods and Labeling”.
- ISO 17665-1:2016 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device(s)				Predicate Device(s) K201993	Reference Device K161213	Remark
Device name	Endo Motor				E-connect S Endo Motor with built-in Apex Locator	XSmart iQ	/
Device model	C-SMART-I PRO	C-SMART-I PILOT	C-SMART-MINI AP	C-Smart-mini	E-connect S	XSmart iQ	/
Classification Regulation	21CFR 872.4200				21CFR 872.4200	21CFR 872.4200	SAME
Classification	Class I				Class I	Class I	SAME
Product Code	EKX/LQY				EKX/LQY	EBW	Same with the Predicate Device
Common Name	endodontic treatment motorized handpiece/ root canal apex locator				endodontic treatment motorized handpiece/ root canal apex locator	Dental hand-piece and accessories	Same with the Predicate Device
Indications for use	**C-SMART-I PRO, C-SMART-I PILOT, C-SMART-MINI AP:** The Endo Motor device is an endodontic treatment motorized handpiece with root canal measurement capability. It can be used to enlarge the canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device for measuring canal length. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.				E-connect S is a cordless endodontic treatment motorized handpiece with root canal measuring capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can	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.	SAME The root canal measurement capability is only same with the Predicate Device.

	C-Smart-mini: The Endo Motor device is an endodontic treatment motorized handpiece. It can be used to enlarge the canals . It can be used as a low-speed motorized handpiece.This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.				be used as a low-speed motorized handpiece and device for measuring canal length.This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.		
Patient populations	Adult				Adult	Adult	SAME
Anatomical sites	Root canal, softened dentin				Root canal, softened dentin	Root canal, softened dentin	SAME
Where used	Dental clinic, University hospital and the other clinical settings				Dental clinic, University hospital and the other clinical settings	Dental clinic, University hospital and the other clinical settings	SAME
Technical Specifications							
Energy used and/or delivered	Li-ion battery (DC 7.4V)	Li-ion battery (Control unit: DC7.4V Motor handpiece: DC3.7V)	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	Li-ion battery (DC 3.7V)	Lithium ion battery: 3.6V	Difference (1)
Charger Power Supply	AC 100-240V 50-60 Hz	AC 100-240V 50-60 Hz	AC 100-240V 50-60 Hz	AC 100-240V 50-60 Hz	Unknown	AC 100-240 Volts 50-60 Hz	Same with the Reference Device
Display	LCD Control unit display with	LCD Control unit display with	LCD Motor Handpiece	LCD Motor Handpiece	OLED Motor Handpiece display with button	iPad Mini® display with iPad Mini® application	Difference (2)

	membrane keypad	touch screen and button	display with button	display with button		(Endo iQ app)	
	LCD screen for visual selection of parameters such as speed, torque, working mode, apex position, etc.	LCD screen for visual selection of parameters such as speed, torque, working mode, apex position, etc.	LCD screen for visual selection of parameters such as speed, torque, apex position, etc.	LCD screen for visual selection of parameters such as speed, torque, rotary files program, etc.	OLED screen for visual selection of parameters such as speed, torque, files program, apex position, etc.	iPad Mini® application (Endo iQ app) with predefined torque and speed settings.	
Features	Corded motor hand-piece	Cordless motor hand-piece	Cordless motor hand-piece	Cordless motor hand-piece	Cordless motor hand-piece	Cordless motor hand-piece	Difference (3)
	Continuous rotation and reciprocating movement				Continuous rotation and reciprocating movement	Continuous rotation and reciprocating movement	SAME
	root canal measurement	root canal measurement	root canal measurement	N/A	root canal measurement	N/A	Same with the Predicate Device
Operation Mode	M1 mode: Apex locator only. M2 mode: Motor only. M3 mode: (Dual mode) Motor with apex location function.	Endo motor mode: root canal preparation . Apex locator mode: root canal length measurement . Multi-function mode: undertake root canal measurement and	Endo motor mode: Prepare the root canal, without apex locator function. Apex Locator mode: Measure the length of the root canal, without motor function. Multi-function	Endo motor mode	Endo Motor mode/ Apex mode	Not Available	Difference (4)

		preparation .	mode: Measuring the length while root canal preparation.				
Safety Mechanisms	During operation when the load reaches the preset torque limit value , the motor will automatically rotate in the reverse direction .				Unknown	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.	Same with the Reference Device
Exterior Design	136.1 x 135.6 x 118.5mm(Control unit) 201.4 x 32.9 x21.4mm (Motor handpiece include Contra angle)	201.4 x 111.2 x 64.6mm(Control unit) 201.8 x 31.4 x28mm (Motor handpiece include Contra angle)	209.2 x 33.8 x 30mm (Motor handpiece include Contra angle) 66 x ϕ 90.4mm (Battery Charger)	217.45 x 28.18 x 26mm (Motor handpiece include Contra angle) 39.6 x ϕ 80mm (Charging Base)	21.5cm×17.5cm×9cm	206 mm X 24.6 mm X 24.8 mm	Difference (5)
Speed	150-650rpm	150-1000rpm	150-600rpm	125-625rpm	120-1000 rpm	1200 - 5100 RPM (in rotary mode)	Difference (6)
Torque	0.6-5.2 N.cm	0.6-3.9 N.cm	0.6-3.9 N.cm	0.6-3.9 N.cm	0.5N·cm-4N·cm	50-510 gram-cm	Difference

							(7)
Accuracy of the root apex locator function	±0.5mm	±0.5mm	±0.5mm	No root apex locator function	-0.5mm to+0.5mm for Apex position	N/A	Same with the Predicate Device
Spray Nozzle	Spray nozzle				Spray nozzle	Spray nozzle	SAME
Bluetooth	No Bluetooth	Bluetooth 4.0 low energy (communication between the control unit and motor handpiece)	No Bluetooth	No Bluetooth	No Bluetooth	Bluetooth 4.0 low energy (communication between the Apple iPad and motor handpiece)	Difference (8)
Wireless charging	N/A	Wireless charging			N/A	N/A	Difference (9)
Sterility	Contra angle, File clip , Lip hook and lighting device are sterilized with steam sterilization process.	Contra angle, File clip and Lip hook are sterilized with steam sterilization process.	Contra angle, File clip and Lip hook are sterilized with steam sterilization process.	Contra angle and lighting device are sterilized with steam sterilization process.	Contra Angle, Lip Hook, File clip, Insulating Sleeve autoclavable.	Contra Angle are sterilized	Same with the Predicate Device

Patient Contacting Materials	Contra angle: Copper and 304 Stainless steel; File clip: Plastic PI and 304 Stainless steel; Lip hook: 304 Stainless steel; Lighting device: Plastic PPSU	Contra angle: Copper and 304 Stainless steel; File clip: Plastic PI and 304 Stainless steel Lip hook: 304 Stainless steel	Contra angle: Copper and 304 Stainless steel; File clip: Plastic PI and 304 Stainless steel; Lip hook: 304 Stainless steel	Contra angle: Copper and 304 Stainless steel; Lighting device: Plastic PPSU	Used materials conform to ISO10993.	Used materials conform to ISO10993.	Difference (10)
Applied Standards:							
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO10993-11				ISO 10993-5 ISO 10993-10 ISO10993-11	ISO 10993-5 ISO 10993-10	Same with the Predicate Device.
Electrical Safety	IEC 60601-1				Conform to IEC60601-1	Conform to IEC60601-1	SAME
Mechanical safety	IEC 60601-1				Conform to IEC60601-1	Conform to IEC60601-1	SAME
Thermal safety	IEC 60601-1				Conform to IEC60601-1	Conform to IEC60601-1	SAME
EMC	IEC 60601-1-2				Conform to IEC60601-1-2	Conform to IEC60601-1-2	SAME
Performance	IEC 80601-2-60 ISO 14457				IEC 80601-2-60 ISO 14457	IEC 80601-2-60 ISO 14457	SAME
Material of the applicable root canal files	Nickel titanium (NiTi)				Unknown	Unknown	Difference (11)
Barrier sleeve	The body of the handpiece is to be covered with a FDA cleared barrier sleeve.				The body of the handpiece is to be covered with a FDA cleared	Single use barrier covers for the iPad Mini® and motor	Same with the Predicate

		barrier sleeve.	hand-piece.	Device

Analysis:

Difference (1):

There is difference in the battery voltage, the proposed device includes two voltage types, but the design of subject device comply with electrical safety standard IEC/AAMI 60601-1, and its Li-ion battery comply with the battery safety standard IEC 62133, so the differences in voltage would not affect its safety and effectiveness.

Difference (2):

There is difference in the display, all the proposed device, predicate device and reference device could display the parameter information, pre- and post-operation information, so such difference would not affect its safety and effectiveness.

Difference (3):

The C-SMART-I PRO model of the proposed device is a corded motor handpiece, other models are cordless motor handpiece which are the same as compared to the predicate device and reference device, the corded design of C-SMART-I PRO model comply with electrical safety standard IEC/AAMI 60601-1 and EMC standard IEC 60601-1-2, so the difference would not affect its safety and effectiveness.

Difference (4):

Compared with the predicate device, the C-SMART-I PRO, C-SMART-I PILOT and C-SMART-MINI AP models of the proposed device have Multi-function mode/Dual mode (ie. measuring the length while root canal preparation). Although the two modes work at the same time, they work in the same way as the single mode, and the proposed device comply with electrical safety standard IEC/AAMI 60601-1 and EMC standard IEC 60601-1-2, the difference would not affect its safety and effectiveness.

Difference (5):

The proposed device has difference in dimension with the predicate device, this is a different appearance and would not affect the performance and safety.

Difference (6):
The rotation speed of the proposed device is within the speed of the predicate device, thus substantially equivalent, the difference would not affect its safety and effectiveness.

Difference (7):
There is minor difference in the torque setting range as compared to the predicate device, however it is adjustable in the main unit by the operator, the device provides auto reverse and stop function when motor bear the torque resistance higher than the setting torque; and the device comply with IEC80601-2-60 requirement. This difference would not affect its safety and effectiveness.

Difference (8):
Bluetooth provides a means of communication for the C-SMART-I PILOT motor handpiece to connect to the control unit. The Bluetooth function is substantially equivalent as compared to the reference device. The Bluetooth function of the proposed device C-SMART-I PILOT is tested according to the FCC standards, and we have conducted bench testing and Bluetooth working distance testing for the Bluetooth function, verified that Bluetooth function can be used normally and will not affect or reduce the performance of the product, so the Bluetooth function would not affect its safety and effectiveness.

Difference (9):
Wireless charging is a charging way for motor handpiece of C-SMART-I PILOT /C-SMART-MINI AP/C-Smart-mini models. The product does not work during wireless charging, we have conducted bench testing for the Wireless charging function of these models, verified that Wireless charging function can normally charge the device and will not affect or reduce the performance of the product, so the Wireless charging function would not affect its safety and effectiveness.

Difference (10)
The patient contacting materials of the predicate device and the reference device are unknown, however both the Patient contacting components materials of proposed device and predicate device meet the ISO10993-5 &ISO10993-10 and ISO10993-11 standard, the difference would not affect its safety and effectiveness.

Difference (11)

The material of root canal files that can be used with the predicate device and the reference device are unknown, however, a clinical accuracy study was conducted on the proposed device and root canal file of Nickel titanium (NiTi) material, the result meet the requirement of ±0.5mm measurement accuracy, so the difference would not affect its safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate devices.