July 24, 2024

Dentsply Sirona Inc.
Laura Sobrin
Regulatory Affairs Manager, Corporate
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K233865
Trade/Device Name: X-Smart Pro; X-Smart Pro+
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX, LQY
Dated: June 28, 2024
Received: June 28, 2024

Dear Laura Sobrin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233865

Device Name

X-Smart Pro;
X-Smart Pro+

Indications for Use *(Describe)*

The Endo Tabletop consists of a motorized endodontic handpiece for root canal cleaning and preparation. In addition, some models may also incorporate an electronic apex locator that assists the operator to locate the file tip in the root canal. The Endo Tabletop is intended solely for use by trained dental professionals on patients that need root canal treatment.

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.

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510(k) #: K233865

510(k) Summary

Prepared on: 2024-07-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dentsply Sirona Inc.
Applicant Address	221 West Philadelphia Street, Suite 60W York PA 17401 United States
Applicant Contact Telephone	717-849-4434
Applicant Contact	Ms. Laura Sobrin
Applicant Contact Email	Corporate-RA@dentsplysirona.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	X-Smart Pro; X-Smart Pro+
Common Name	Dental handpiece and accessories
Classification Name	Handpiece, Direct Drive, Ac-Powered
Regulation Number	872.4200
Product Code	EKX, LQY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202906	EndoPilot2	ELC, EKX, EK
K151045	Teneo Dental treatment unit and accessories	EIA
K150750	Endo 6:1, T1 Line Endo 6 L, SIRONiTi Apex, T1 Spray	EGS
K111078	AEU-26L ELECTRONIC ENDODONTIC SYSTEM (branded as P	EKX

Device Description Summary

21 CFR 807.92(a)(4)

The Endo Tabletop is designed to drive dental endodontic instruments for a rotating treatment of root canals. Therefore, the Endo Tabletop provides different kinds of movement:

1. Continuous rotary motions (adjustable speed, torque and direction depending on the file used)
2. Reciprocating motions (speed, torque, direction, and angles depending on the file used)

This functionality is provided by a Brushless Direct Current (BLDC) motor having speed and torque controls. The motor speed control is driven by a dedicated controller using pulse width modulation (PWM) of the excitation voltage and the motor torque control is performed by controlling and limiting the maximum current flow. The contra-angle transmits the motor movement in speed and direction to the endodontic file.

The user can set the device by a graphical user interface on a 7" touch Thin-Film Transistor (TFT) display. The handpiece can be started/ stopped with a finger switch and foot control.

All models can also be used for root canal length determination using the integrated apex locator functionality. This apex locator

functionality is provided by evaluating the electrical impedance between the file tip, attached to the file clamp, placed into the dental root canal and the lip clip placed on the mucosa of the patient. The results of this estimation must be confirmed by standardized diagnostic imaging like an X-ray.

The proposed apex locator function has two modes: standalone and combined mode. In standalone mode, the apex determination works with the lip clip and the endodontic file, which is connected to a file clamp. In combined mode, the apex determination works with the lip clip and the endodontic file which is connected to the contra-angle.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Endo Tabletop consists of a motorized endodontic handpiece for root canal cleaning and preparation. In addition, some models may also incorporate an electronic apex locator that assists the operator to locate the file tip in the root canal. The Endo Tabletop is intended solely for use by trained dental professionals on patients that need root canal treatment.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Indications for Use of the proposed device are very similar as the predicate EndoPilot2 (K202906) with the exception that the predicate device includes additional functionality that is not covered by the proposed device, such as the dental obturator to fill and pressurize the root canal and the ultrasonic-handpiece for root-canal cleaning and preparation. Besides these additional functions that are part of the predicate device (K202906), the proposed and predicate device have the same indications to clean and prepare the root canal and to detect the apex location.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed device and predicate device (K202906) share apex location and endodontic root canal preparation functionalities.

The proposed and predicate device use established apex location determination technology which evaluates the electrical impedance between the file tip placed into the dental root canal and the lip clip placed on the mucosa of the patient. Both devices allow for two methods: Apex location via a file clamp without the handpiece or via a fully inserted contra-angle handpiece. The accuracy of the apex location is the same, at ≤ 0.5 mm. Both devices share similar components, including lip clip, file clamp, file clamp cable, adapter cable and a contra-angle/motor handpiece for apex measurement.

The proposed device and predicate device use a 7" inch graphical user interface with touch screen. While the predicate device's graphical user interface uses a Liquid-crystal display (LCD) touchscreen, the proposed device uses Thin Film Transistor (TFT) technology. Different touch displays do not affect the performance of the devices. The main unit including the touch screen and device control of both the proposed and predicate devices contains a database with preset values for parameters for selecting endodontic files from different file manufacturers. Both units provide acoustic signals for file position indication and torque indication, as well as error and notification sounds.

The proposed device has an integrated LED light on the contra-angle to help with illumination of the area of treatment, which is similar to the integrated light in reference device, K150750. In addition, the contra-angle in both devices holds the endodontic files used in endodontic root canal preparation procedures. Therefore, both devices support endodontic files in accordance with ISO 1797 Type 1. Although the predicate device uses a standard interface that allows for the use of third-party contra-angles, the proposed device can only be used with the supplied contra-angle. The proposed device includes a handpiece sleeve that covers the motor for contamination protection between patients, which is not a component available with the predicate device.

File performance (speed/torque) is determined by the output of the system consisting of contra-angle and motor together. The gear ratio is different between the proposed (5:1; 3,000 rpm) and predicate (1:1; 1,000 rpm) devices but both ratios are acceptable. Although the gear ratio between the proposed and reference (K111078) devices is different, when converting to the applicable acceptable file speed, the file speed range is similar (3,000 rpm for proposed device and 3,600 rpm for reference device (K111078)). In addition, the proposed device can supply a wider range of torque and rotational speed when compared to the predicate device. This allows for a wider range of endodontic files that can be attached and procedures in which those files can be used. The file rotation speed and torque limits of the proposed device are either within the range of the reference device (K111078) or similar and cover the speed and torque requirements of the instruments, such as files, that are intended to be used with the proposed device. The motor functional specifications are also similar. Both the proposed and predicate motors have continuous rotation or reciprocation movement, auto-reverse function, speed control and torque control.

Although the proposed and predicate devices have the same energy input, the rated maximum current output of the power supplies is higher on the proposed device. The output current is mainly used to speed up the charging of the motor within device specifications. To ensure safety, the proposed device uses a medical power supply certified according to IEC 60601-1:2020. Furthermore, the proposed device's nominal energy of the Lithium-ion battery is lower but sufficient power for the indicated procedures and was tested according

to UN 38.3 and IEC 62133-2:2017. Both the proposed and predicate device meet electrical safety requirements of IEC 60601-1 and IEC 80601-2-60, electromagnetic compatibility requirements of IEC 60601-1-2, and are Class II equipment, Type BF applied part.

Device activation is also similar between the proposed device and the predicate device (K202906). The proposed device allows for the operation of the handpiece via a finger switch and footswitch, while the predicate device allows operation via the footswitch. The proposed device also allows for a wireless connection for service/maintenance purposes.

Any differences between the proposed, predicate (K202906) and reference (K111078, K150750) devices described above were verified via performance testing, biocompatibility, software testing, reprocessing testing, and electromagnetic compatibility and safety testing. The results of testing confirmed that the proposed Endo Tabletop is substantially equivalent to the predicate device EndoPilot2 (K202906) and reference devices (K111078, K150750) and the differences do not raise new questions regarding safety and performance.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

To confirm the performance of the handpiece according to ISO 14457:2017 (Dentistry- Handpieces and motors) and FDA guidance document, Dental Handpieces - Premarket Notification [510(k)] Submissions, testing was performed according to ISO 14457:2017. All testing to the applicable elements of the standard passed.

There are no clinical tests submitted, referenced or relied on in the 510(k) for a determination of substantial equivalence.

To demonstrate the performance of the proposed Endo Tabletop and to show substantial equivalence to the predicate device, EndoPilot2 (K202906) and reference devices (K111078, K150750), in addition to the performance testing referenced above, non-clinical testing was conducted. Results confirm that the design inputs, function, and performance specifications for the proposed device are met.

• Biocompatibility evaluation was performed per:
o ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
o ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
o ISO 10993-10: 2021, Biological evaluation of medical devices, Part 10: Tests for Skin Sensitization
o ISO 10993-23: 2021, Biological evaluation of medical devices, Part 23: Tests for Irritation
o FDA Guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

• Electrical safety testing was performed per:
o IEC 60601-1-6:2010/AMD2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
o IEC 80601-2-60:2019, Medical electrical equipment - Part 2: Particular requirements for basic safety and essential performance of dental equipment
o IEC 62471:2008, Photobiological safety of lamps and lamp systems
o IEC 60601-1:2012/AMD2:2020, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
o UN 38.3, Certification for Lithium Batteries
o IEC 62133-2:2017, 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.

• Electromagnetic compatibility testing was performed per:
o IEC 60601-1-2:2014/AMD1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
o IEC TR 60601-4-2:2016, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

• Reprocessing validation (cleaning, disinfection, and/or sterilization) testing was performed per:
o FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."
o TIR 12:2020, Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers
o TIR 30:2011, R2016, A Compendium Of Processes, Materials, Test Methods, And Acceptance Criteria For Cleaning Reusable Medical Devices
o ANSI/AAMI ST98:2022, Cleaning validation of health care products – Requirements for development and validation of a cleaning process for medical devices
o ISO 17665-1, 1st Ed, 2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices.

• Software verification and validation testing is included based on a Basic Documentation Level software and was performed per:

o IEC 62304:2006 + A1:2015, Medical device software, Software life-cycle processes
o FDA guidance document “Guidance for the Content of Premarket Submissions for Device Software Functions”.

• Cybersecurity risk assessment was performed per FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

Minor differences in the technological characteristics were evaluated through appropriate performance testing which demonstrates that the proposed device, when compared to the predicate device (K202906) and reference devices (K111078, K150750), does not raise new questions regarding safety and effectiveness. Therefore, performance data support the conclusion that the proposed device performs as well as the predicate device EndoPilot2 (K202906).