August 25, 2025

Dentsply Sirona Inc.
Diane Rutherford
Director Regulatory Affairs
221 West Philadelphia St
Suite 60W
York, Pennsylvania 17401

Re: K251811
Trade/Device Name: Motor and Apex Module (MaAM)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW, EKX, LQY
Dated: June 12, 2025
Received: June 12, 2025

Dear Diane Rutherford:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251811

Please provide the device trade name(s).

Motor and Apex Module (MaAM)

Please provide your Indications for Use below.

The Midwest Motor Control Module includes a control unit, ports for three motors, an apex location port, and a peristaltic pump port. The motor ports are compatible with the Midwest Power Lux and Midwest Power Lux Implant.

The Midwest Power Lux electric micromotor is intended for use as a drive for rotating and oscillating straight and contra-angle hand pieces for endodontic and general dental purposes.

The Midwest Power Lux Implant motor is intended for use in implant placement and includes a closed system for delivery of sterile solution via peristaltic pump operation.

The apex locator supports the dentist in the determination of the working length during the endodontic treatment.

These motors are to be driven by the control unit. The control unit is an internal component of a dental delivery system.

The use of this product is intended exclusively for duly qualified dental practitioners.

Please select the types of uses (select one or both, as applicable).

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

510(k) #: **K251811**

510(k) Summary

Prepared on: 2025-06-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Dentsply Sirona Inc
Applicant Address	221 West Philadelphia St Suite 60W York PA 17401 United States
Applicant Contact Telephone	+1-704-458-1942
Applicant Contact	Ms. Diane Rutherford
Applicant Contact Email	diane.rutherford@dentsplysirona.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Motor and Apex Module
Common Name	Dental handpiece and accessories
Classification Name	Controller, Foot, Handpiece And Cord
Regulation Number	872.4200
Product Code(s)	EBW, LQY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K163131	A-dec NLZ Electric Motor System	EBW
K150909	Motor BL ISO E (a physical part of Intego)	EIA
K151045	Motor BL Implant (a physical part of Teneo)	EIA
K233865	X-Smart Pro; X-Smart Pro+	EKX

Device Description Summary

21 CFR 807.92(a)(4)

This device is a system that includes a control module (internal component of a dental delivery system) that can operate up to three dental motors, an apex locator, and a peristaltic pump. The motors do not operate concurrently. The motors that can be attached include dental motors and dental implant motors. The motors included with this module in this subject system are the Midwest Power Lux and Midwest Power Lux Implant. Also included is the cable, file, and lip clip required for the operation of the apex location technology. The programming supports manual use of the apex locator as well as combined use of the locator with a motor. The included peristaltic pump and control allows for sterile solution irrigation when required.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Midwest Motor Control Module includes a control unit, ports for three motors, an apex location port, and a peristaltic pump port. The motor ports are compatible with the Midwest Power Lux and Midwest Power Lux Implant.

The Midwest Power Lux electric micromotor is intended for use as a drive for rotating and oscillating straight and contra-angle hand pieces for endodontic and general dental purposes.

The Midwest Power Lux Implant motor is intended for use in implant placement and includes a closed system for delivery of sterile solution via peristaltic pump operation.

The apex locator supports the dentist in the determination of the working length during the endodontic treatment.

These motors are to be driven by the control unit. The control unit is an internal component of a dental delivery system.

The use of this product is intended exclusively for duly qualified dental practitioners.

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

The proposed and predicate devices are intended for the same clinical use. Minor variations exist in the way the indications are described, but those variations do not impact the clinical use, safety or effectiveness of the device.

Technological Comparison 21 CFR 807.92(a)(6)

The Midwest Motor Control Module includes a control module (internal component of a dental delivery system) that can operate up to three dental motors, an apex locator, and a peristaltic pump. The motors do not operate concurrently. The motors that can be attached include dental motors and dental implant motors and are only able to be operated in conjunction with the control module; the motors are integral components of the system. The motors included with this module are the Midwest Power Lux and Midwest Power Lux Implant. Also included is the cable, file, and lip clip required for the operation of the apex location technology. The programming supports manual use of the apex locator as well as combined use of the locator with a motor. The included peristaltic pump and control allows for sterile solution irrigation when required.
The Midwest Motor Control Module and motors have the same technological characteristics as the predicate and reference devices. Both provide a controller to operate electric micromotors for dental procedures performed by qualified dental practitioners. The control module is contained within the dental delivery system and acquires electrical power from the delivery system. Users control the motor system through the delivery system interfaces. The control module receives instructions from the interface such as motor rotation/stop, speed setting value, torque setting value, and LED turning ON/OFF. The control module drives the motors via the motor tubing.
For Apex location, 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 hand piece or via a compatible contra-angle handpiece. Both devices share components, including lip clip, file clamp, file clamp cable, adapter cable for apex measurement.

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

Testing in accordance to ISO 14457 for the dental motors.
Testing in accordance with IEC 62471:2006, Photobiological safety of lamps and lamp systems
Testing in accordance with ISO 3964:2018 AMD1:2018, Dental coupling dimensions

Not applicable (no clinical data necessary)

All testing demonstrated the proposed device to meet specifications and therefore, equivalent to the identified predicate device(s).