



August 22, 2025

Advanced Technology Research (A.T.R.) s.r.l.  
Lorenzo Baroncelli  
Quality and Regulatory Manager  
Via San Donato 345  
Pistoia, PT 51100  
ITALY

Re: K243692

Trade/Device Name: EnDrive (EnDriveUS)  
Regulation Number: 21 CFR 872.4200  
Regulation Name: Dental Handpiece And Accessories  
Regulatory Class: Class I, reserved  
Product Code: EKX, LQY  
Dated: November 29, 2024  
Received: November 29, 2024

Dear Lorenzo Baroncelli:

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](mailto: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

Submission Number (if known)

K243692

Device Name

EnDrive (EnDriveUS)

Indications for Use (Describe)

EnDrive is a battery-operated electronic medical device used for the treatment of root pulp infection, which allows root canal preparation by means of continuously or alternately rotating endodontic instruments with torque control, or retreatment of an already treated tooth, with integrated apex locator.

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) #: K243692

# 510(k) Summary

Prepared on: 2025-08-20

## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name

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Applicant Contact

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## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name

EnDrive (EnDriveUS)

Common Name

Dental handpiece and accessories

Classification Name

Handpiece, Direct Drive, Ac-Powered

Regulation Number

872.4200

Product Code(s)

EKX, LQY

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #

Predicate Trade Name (Primary Predicate is listed first)

Product Code

K220829

Endo Motor

EKX

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

EnDrive is a battery-operated electronic medical device used for the treatment of root pulp infection, which allows root canal preparation by means of continuously or alternately rotating endodontic instruments with torque control, or retreatment of an already treated tooth, with integrated apex locator. We can identify two different functional principles: one is the motor function which serves to shape the root canal the other is the apex locator function to determine the apex approach when the file is in the root canal. The motor function, when the file has a movement transmitted from the motor through the contra-angle, allows the proper shaping of a root canal with infected pulp through rotary or reciprocating movement, helping to remove debris and infected tissue from the canal. The motor, controlled in speed and torque, uses brushless DC technology with 3 phases and 3 Hall sensors, driven by an embedded software. The apex locator function allows to determine when, during an endodontic treatment, the tip of an endodontic instrument, in steel or nickel-titanium, inserted by the dentist inside the root canal, is at the apex of the canal. Two electrodes are applied to the patient, a lip clip on the lip and a file clamp to the endodontic instrument positioned inside the canal. When the device signals the apex has been reached, the dentist positions the instrument stopper on the dental crown and indirectly goes to measure the working length of the canal using a ruler for endodontic instruments, so the length from which the dentist must remove the infected pulp.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

EnDrive is a battery-operated electronic medical device used for the treatment of root pulp infection, which allows root canal preparation by means of continuously or alternately rotating endodontic instruments with torque control, or retreatment of an already treated tooth, with integrated apex locator.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The intended use of the two devices are equivalent, in fact:

EnDrive intended use: EnDrive is a battery-operated electronic medical device used for the treatment of root pulp infection, which allows root canal preparation by means of continuously or alternately rotating endodontic instruments with torque control, or retreatment of an already treated tooth, with integrated apex locator.

Endo Motor intended use: 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.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The EnDrive motor 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 battery used for the handpiece and NiMH battery for the control unit; the control unit is charged by a medical adapter. LCD displays parameters such as selected NiTi file, speed, torque, apex position, etc. Users can also set and modify the settings using the touch screen.

The handpiece connects automatically to the control unit via Bluetooth.

The EnDrive is an endodontic treatment motorized equipment 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 accessories of EnDrive (contra-angle, file clamp and lip clip) are intended to be sterilized prior to use.

The material composition of root canal files that can be used with the EnDrive 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.

The subject device, and the predicate device, C-SMART-I Pilot (K220829), share the same intended use as motorized endodontic handpieces with integrated apex locator capability. Both are intended for root canal preparation and canal length measurement in dental clinical settings, operated by qualified dental professionals. The anatomical site of use (root canal and softened dentin) and the clinical environment (dental clinics, hospitals, university settings) are identical. The two devices are based on the same fundamental technology, consisting of a cordless motorized handpiece powered by an internal rechargeable battery, coupled with a control unit that provides real-time display of operating parameters such as speed, torque, and apex position. Both devices support continuous rotation and reciprocating movements, as well as multiple operating modes: endo motor, apex locator, and combined multifunction mode.

Safety mechanisms are equivalent, including automatic reverse rotation when preset torque thresholds are reached. The subject device and predicate device are highly similar in their technical performance characteristics. Both achieve root canal length measurement accuracy within  $\pm 0.5$  mm and use nickel-titanium (NiTi) files. Accessories such as contra-angle, file clamp, and lip clip are designed for sterilization prior to use, in line with standard infection control requirements. Both devices require the usage of a barrier sleeve on the handpiece body to prevent cross-contamination.

Some minor differences exist between the devices:

Power supply: the EnDrive control unit uses a NiMH battery at 12V, compared to the 7.4V Li-ion battery of the predicate.

User interface: EnDrive incorporates a touch screen interface with a single power button, while the predicate combines a touchscreen with additional physical buttons.

Physical dimensions differ slightly for both control unit and handpiece, but these variations do not alter function.

Performance ranges: EnDrive operates at 250–1000 rpm (vs. 150–1000 rpm) and 0.4–5.0 N-cm torque (vs. 0.6–3.9 N-cm). These ranges overlap and ensure equivalent clinical performance.

Charging method: EnDrive charges via cable connection between the control unit and handpiece, while the predicate supports wireless charging. Both methods have been demonstrated to be safe and effective.

Spray nozzle: EnDrive includes a nozzle for lubrication of the contra-angle, while the predicate also incorporates a spray nozzle; these differences are accessory-related and have no impact on performance.

Patient-contacting materials: EnDrive maintains direct patient contact only through the stainless-steel lip clip, while indirect patient contact may occur via the contra-angle and file clamp. Biocompatibility testing has been completed for the direct and indirect patient-contacting components in accordance with ISO 10993-1, -5, and -18.

Applied standards: minor variations exist in referenced biocompatibility and performance standards, but both devices comply with the relevant ISO and IEC standards for electrical, mechanical, and thermal safety, as well as EMC requirements.

Firmware updates: EnDrive supports software updates via Wi-Fi, while the predicate does not specify such a feature.

These differences are minor in nature, have been verified through bench testing and design validation, and do not raise new safety or effectiveness concerns.

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

Based on the bench test reports assessing the apex locator, motor speed and torque accuracies, the subject device is substantially equivalent based on the following:

- The motor speed range for the subject device is 250-1000 rpm, which is within the range of the predicate device (150-1000 rpm)
- The accuracy of the root apex locator function for the subject and predicate devices is  $\pm 0.5\text{mm}$
- The torque is between 0.4 - 5.0 N cm for the subject device is slightly different from that of the predicate (0.6 - 3.9 N cm), but this difference is minor and does not impact substantial equivalence between the two devices.

In addition to these key features that have been tested, biocompatibility, EMC, reprocessing, and device specific performance tests were conducted for the subject in accordance with the following standards:

- ISO 10993-1:20128
- ISO 10993-5:2009
- ISO 10993-18:2020
- ISO 10993-23:2021
- IEC 60601-1:2020
- IEC 60601-1-2:2020
- IEC 62133-2:2017
- ISO 14457:2017
- ISO 17665-1:2006
- ISO 17664-1:2021