April 24, 2025

Shenzhen Rogin Medical Co., Ltd.
℅ Salon Chen
System Engineer
IMD Medical & Drug Technology Service Institutions
Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District
Dongguan, Guangdong 523039
CHINA

Re: K242514
Trade/Device Name: Endo Motor (E-LITE MAX, E-LITE PRO, E-LITE INO)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: September 25, 2024
Received: March 26, 2025

Dear Salon Chen:

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
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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)*

K242514

Device Name

Endo Motor (E-LITE MAX, E-LITE PRO , ELITE-INO)

Indications for Use *(Describe)*

Endo Motor with E-LITE MAX, E-LITE PRO and ELITE-INO is cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used for preparation and enlargement of root canals, or measuring the canal length. And it can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

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.***

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**510(k) Summary**
**K242514**

## 1. Sponsor Identification:

- Company Name: Shenzhen Rogin Medical Co., Ltd.
- Address: 5th Floor, Block Block I, Jinchangda Science Park, Shangwei Industry District, Shangkeng Community, Guanhu Street, Longhua Distrct, Shenzhen Guangdong, China 518110.
- Phone: +86-755- 26758272
- Fax: +86-755- 26758272
- Contact Person (Title): Nature Xu (General Manager)
- E-mail: admin@rogindental.com
- Date of Preparation: April 23, 2025

## 2. Name of the Device:

- Trade name: Endo Motor
- Model: E-LITE MAX, E-LITE PRO, ELITE-INO

## 3. Common Name and Classification:

- Trade/Proprietary Name: End Motor
- Device Classification Name: Handpiece, Direct Drive, Ac-powered
- Regulation Classification: Dental Handpiece and Accessories
- Product Code: EKX
- Regulation Number: 872.4200
- Class: Class 1
- Review Panel: Dental

## 4. Predicate Device Information:

- 510(k) Number: K203320
- Sponsor: Guilin Woodpecker Medical Instrument Co., Ltd.

- Trade/Proprietary Name: Endo Motor
- Device Classification Name: Handpiece, Direct Drive, Ac-powered
- Device Description: Dental Handpiece and accessories
- Classification Product Code: EKX
- Regulation Number: 21 CFR 872.4200
- Class:1
- Review Panel: Dental

## 5. Application Correspondent


- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person (Title): Salon Chen (System engineer)
- E-mail:33999439@qq.com
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China


## 6. Device Description

**E-LITE MAX & ELITE-INO:**

The Endo Motor with E-LITE MAX and ELITE-INO is a low-speed rotating oral equipment mainly used for root canal preparation and root canal measurement. It is designed to enlarge the root canal, facilitate dentin filling, or measuring the root canal length. The product is a portable device consist of a cordless hand-piece and a charge base, it is powered by built-in lithium batteries and charged by the adapter. LCD displays parameters such as speed, torque, file system, Apex etc. Users can also set and modify by keys, and provide design of factory initialization, and calibration of the apex location. It can be used as a low-speed motorized handpiece and device for measuring canal length. The rotary speed and torque range are adjustable.

There are three function features for E-LIT MAX and ELITE-INO:

- Root Canal enlargement: Prepare the root canal with apex locator function.
- Apex Location: Measure the length of the root canal.
- Multi-function: Measuring the length while root canal preparation.

The device can save 9 programs, each program can set different parameters according to the user.

**E-LITE PRO:**

The Endo Motor with E-LITE PRO is a low-speed rotating oral equipment mainly used for root canal preparation. It is designed to enlarge the root canal or facilitate dentin filling. The product is a portable device having a cordless hand-piece with a charging adapter, it is powered by built-in lithium batteries and charged by the adapter. LCD displays parameters such as speed, torque, file system, Apex etc. Users can also set and modify by keys, and provide design of factory initialization, and calibration of the apex location. It can be used as a low-speed motorized handpiece and device for measuring canal length. The rotary speed and torque range are adjustable.

There is only one function features for E-LITE PRO:

- Root Canal enlargement: Prepare the root canal, without apex locator function.

The device can save 9 programs, each program can set different parameters according to the user.

The Endo Motor must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

The Endo Motor is intended to be sterilized prior to use.

The compatible device can be used with Endo Motor is rotary instruments such as rotary root canal files, the working part of rotary instruments normally made of Nickel titanium (NiTi). These files are not included in the submission.

## 7. Indications for Use

Endo Motor with E-LITE MAX, E-LITE PRO and ELITE-INO is cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used for

preparation and enlargement of root canals, or measuring the canal length. And it can be used to enlarge the canals while monitoring the position of the file tip inside the canal.

## 8. Comparison to the predicate device

### 8.1. Table 1 General Comparison

| Elements of Comparison | Proposed Device | Predicate Device | Judgment |
|---|---|---|---|
| **Company Name** | Shenzhen Rogin Medical Co., Ltd. | Guilin Woodpecker Medical Instrument Co., Ltd. | / |
| **Device Trade Name** | Endo Motor | Endo Motor | / |
| **Device Common Name** | Handpiece, Direct Drive, Ac-powered | Handpiece, Direct Drive, Ac-powered | SE |
| **Classification Product Code** | EKX | EKX | SE |
| **Regulation** | 21 CFR 872.4200 | 21 CFR 872.4200 | SE |
| **Regulation Description** | Dental handpiece and accessories | Dental handpiece and accessories | SE |
| **Review Panel** | Dental | Dental | SE |
| **Class** | 1 | 1 | SE |
| **Prescription or OTC** | Prescription Use | Prescription Use | SE |

| | | | |
|---|---|---|---|
| **Anatomical Sites** | Root canal Softened dentin | Root canal Softened dentin | SE |
| **Target Population** | Patients in need of root canal surgery | Patients in need of root canal surgery | SE |
| **Where used** | Dental Clinic<br>University<br>Hospital<br>The other clinical settings | Dental Clinic<br>University<br>Hospital<br>The other clinical settings | SE |
| **Intended Use** | Endo Motor with E-LITE MAX, E-LITE PRO and ELITE-INO is cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used for preparation and enlargement of root canals, or measuring the canal length. And it can be used to enlarge the canals while monitoring the position of the file tip inside the canal. | Endo Motor, Ai-Motor and Endo Radar Plus are cordless endodontic treatment motorized handpiece with root canal measurement capability. It can be used for preparation and enlargement of root canals, or measuring the canal length. And it can be used to enlarge the canals while monitoring the position of the file tip inside the canal. | SE |

### 8.2. Table 2 Safety factor & Performance Comparison

| Safety factor & Performance | Proposed Device | Predicate Device | Judgment |
|---|---|---|---|
| **Electrical Safety** | Compliance with IEC 60601-1 | Compliance with IEC 60601-1 | SE |
| **EMC** | Compliance with IEC 60601-1-2 | Compliance with IEC 60601-1-2 | SE |
| **Usability Engineering** | Compliance with IEC 62366-1 | Compliance with IEC 62366-1 | SE |
| **Software** | Compliance with IEC 62304 | Compliance with IEC 62304 | SE |
| **Biocompatiblity** | Compliance with ISO 10993-1 | Compliance with ISO 10993-1 | SE |

| Safety factor & Performance | Proposed Device | Predicate Device | Judgment |
|---|---|---|---|
| **Dimension** | E-LITE MAX: φ32 (Biggest Diameter) * 150mm (Length)<br>E-LITE PRO: φ30 (Biggest Diameter) * 151mm (Length)<br>ELITE-INO: 30(Biggest Diameter) * 200mm (Length) | Motor Handpiece:<br>Ai- Motor: 28mm x 33.7mm x 199.2m<br>Endo Radar Plus: 27.8mm x 29mm x 212mm | Note 1 |
| **Weigh** | E-LITE MAX 110g<br>E-LITE PRO 120g<br>ELITE-INO: 175g | Ai- Motor: 150g<br>Endo Radar Plus: 151g | Note 1 |
| **power Supply** | Lithium battery (DC3.7) | Lithium battery (DC3.7) | SE |
| **Charger Power Supply** | AC100V-240V | AC100V-240V | SE |
| **Frequency of Supply Voltage** | 50Hz ~ 60Hz | 50Hz ~ 60Hz | SE |
| **Components** | Measuring wire<br>File clip Lip hook<br>Touch probe<br>Tester<br>Spray Nozzle | Measuring wire<br>File clip Lip hook<br>Touch probe<br>Tester<br>Spray Nozzle | SE |
| **Safety Mechanism** | Automatically stops or reversely rotates as soon as the file reaches the apical stop, so as to prevent perforation. | Automatically stops or reversely rotates as soon as the file reaches the apical stop, so as to prevent perforation. | SE |

| Safety factor & Performance | Proposed Device | Predicate Device | Judgment |
|---|---|---|---|
| **Torque Range** | E-LITE MAX：0.6~3.9N·cm<br>ELITE-INO: 0.6~4.0N·cm<br>E-LITE PRO: 0.6~3.9N·cm | 0.4 Ncm ~ 5 Ncm | Note 2 |
| **Rotate Speed** | E-LITE MAX：150~800 rpm<br>ELITE-INO:120 rpm~1200 rpm<br>E-LITE PRO: 150~800 rpm<br>(File in rotary mode) | 100 rpm~1200 rpm<br>(File in rotary mode) | Note 3 |
| **Adjustability of Speed and Torque** | 0.5 Torque setting (Ncm)<br>50 speed steps | 0.5 Torque setting (Ncm)<br>50 speed steps | SE |
| **Micro Motor** | Brushless | Brushless | SE |
| **USB Ports** | Yes | Yes | SE |
| **Primary Contra Angle Gear Ratio** | E-LITE MAX ：16:1<br>ELITE-INO: 6:1<br>E-LITE PRO: 1:1 | 6:1 | Note 4 |
| **Operation Mode** | Continuous operation | Continuous operation | SE |

As shown in the above comparison Table, the proposed device is in similarity to the predicate device. Accordingly, the proposed devices are substantially equivalent to the predicate Endo Motor (K203320).

Design and Technology – The basic design and technology of providing Endo Motor is the same or similar.

Performance and Specifications – The subject device has similar handpiece system and specifications to the predicate device.

Indications – The indication is identical with the predicate device.

**8.3. Review of Differences:**

**Note1:**

There are differences in the handpiece dimensions and weight between the proposed and predicate devices. The proposed devices have a cylindrical handle design with a slightly shorter length compared to the predicates. The proposed devices have passed usability compliance testing for their intended use. The weight reduction, combined with the ergonomic design, does not compromise the device's structural integrity or performance. Therefore, these differences do not introduce any new safety or effectiveness concerns when compared to the predicate devices.

**Note2:**

There is the difference in the torque range as compared to the predicate, 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 requirements, this difference would not affect its safety and effectiveness.

**Note3:**

The rotation speed of the prosed device is within the speed of the predicate device, thus substantially equivalent, the difference would not affect its safety and effectiveness.

**Note4:**

There is the difference in Primary Contra Angle Gear Ratio as compared to the predicate, Contra Angle Gear Ratio is tested, the difference would not affect its safety and

effectiveness.

**9. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The proposed device is the same as the predicate device but the two devices are different. A series of safety and performance tests were conducted on the subject device:

- Biocompatibility Assessment per ISO 10993-1
- Reprocessing Validation (cleaning, disinfection, sterilization)
- Software Validation
- Electromagnetic compatibility and electrical safety
- Function test

All the test results demonstrate the Endo Motor meets the requirements of its pre-defined acceptance criteria and intended uses, and is substantially equivalent to the predicate device.

**10. Clinical Tests Performed**

No clinical test data was used to support the decision of substantial equivalence.

**11. Conclusion**

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject devices are substantially equivalent to the predicate devices.