March 7, 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 City, Guangdong Province
Guangdong, 523039
CHINA

Re: K242383
Trade/Device Name: Apex Locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: February 5, 2025
Received: February 5, 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
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)*
K242383

Device Name
Apex Locator

Indications for Use *(Describe)*

Apex Locator is used to detect the apex of root canal. 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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K242383

510(k) Summary

1. Submitter's Identification:

- Company Name: Shenzhen Rogin Medical Co., Ltd.
- Address: Rm 3109, Bldg 6, Tian'an Cloud Park, Bantian Str, Longgang Dist, Shenzhen, Guangdong, 518129, CHINA.
- Phone: +86-755- 26758272
- Fax: +86-755- 26758272
- Contact Person (Title): Nature Xu (General Manager)
- E-mail: admin@rogindental.com
- Date of Preparation: August 24, 2024

2. Common Name and Classification:

- Device Classification Name: Locator, Root apex
- Classification Product Code: LQY
- Regulation Number: Pre-Amendment
- Class: Unclassified
- Review Panel: Dental
- Device Name: Apex Locator
- Model：APEX-S, APEX-R

3. Predicate Device Information:

- 510(k) Number: K212178
- Device Classification Name: Locator, Root apex
- Sponsor: Foshan COXO Medical Instrument Co., Ltd.
- Classification Product Code: LQY
- Regulation Number: Pre-Amendment
- Class: Unclassified
- Review Panel: Dental

- Device name: Root Apex Locator
- Common Name: Locator, Root Apex

4. 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

5. Device Description

Apex Locator is an oral equipment used for root canal measurements. It features an LCD color display with functional buttons, enabling users to conveniently view parameters such as battery status, test wire connection status, and apex position etc. Users can easily adjust sound level, brightness, and reference settings using intuitive buttons, and perform functional checks of both the device and cable. The device is intended to be sterilized prior to use.

6. Indications for Use

Apex Locator is used to detect the apex of root canal. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

7. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	Shenzhen Rogin Medical Co., Ltd.	Foshan COXO Medical Instrument Co., Ltd.	/
Device Name	Apex Locator	Root Apex Locator	/
Classification Product Code	LQY	LQY	SE
Regulation	N/A	N/A	SE
Classification Name	Dental	Dental	SE
Class	Unclassified	Unclassified	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
Intended Use	Apex Locator is used to detect the apex of root canal. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	The Root Apex Locator is used to detect the apex of root canal. This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	SE

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
power Supply	Lithium battery (DC3.7V)	Lithium battery (DC3.7V)	SE
Charger Power Supply	AC100V-240V	AC100V-240V	SE
Frequency of Supply Voltage	50Hz ~ 60Hz	50Hz ~ 60Hz	SE
Components	Measuring wire File clip Lip hook Touch Probe Tester	Measuring wire File clip Lip hook Touch probe Tester	SE

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Dimensions	APEX-S： Length:106mm Width: 75mm Thickness:24mm APEX-R: Length:110mm Width: 67mm Thickness: 52mm	Length: 110mm Width: 103 mm Thickness: 21.5mm	Difference (1)
Cable length	Charger cable: 1.5m Measuring wire: 1.5m	Charger cable: 1.5m Tester cable: 1.4m	Difference (2)
Weight	APEX-S：540g APEX-R：330g	270g	Difference (3)
Power supply	Li-ion Battery 3.7V, 800mAh	Li-ion Battery DC 3.7V 1800mAh	Difference (4)
Charger	Input: AC 100-240 V, 50/60 Hz Output: DC 5V 1A Classification of Protection against Electric Shock: Class II (adaptor)	Input: AC 100-240 V, 50/60 Hz Output: DC 5V 1A Classification of Protection against Electric Shock： Class II (adaptor)	SE
Means of input	Button control	Touch screen Foldable main unit	Difference (5)

Safety factor & Performance	Proposed Device	Predicate Device	Judgment
Adjustment before measurement	Reference setting function enables to mark an individual predetermined reference position at the required distance from the apex. This variable apical arrow can be set between the first green bar and the last green bar.	The DR'S CHOICE Apical Arrow function enables to mark an individual predetermined reference position at the required distance from the apex. This variable apical arrow can be set between the first green bar and the last yellow bar.	Difference (6)
Measurement Accuracy	±0.5mm	±0.5mm	SE
Patient contacting components materials	Lip hook: Stainless steel; File clip: stainless steel, plastic PBT	Lip hook: 304 Stainless steel; File clip: PI and 304Stainless steel	Difference (7)
Sterilization	Lip clip and file clip are user sterilized by steam sterilization.	Lip clip and file clip are user sterilized by steam sterilization.	SE

Review of Differences：

Difference (1)

The proposed device includes the same main specifications as compared to the predicate device but differs in dimension, which is caused by different appearance design and could not effects the performance and safety.

Difference (2)

There is a difference in the cable length, but these cables include the same function, the cable length difference would not affect its safety and effectiveness.

Difference (3)

The proposed device and the predicate device have a different weight, however, this could not effect the performance and safety.

Difference (4)

Both the proposed device, the predicate device is powered by rechargeable 3.7V Li-ion battery, there is a difference in the battery capacity. The proposed device complies with electrical safety standard IEC 60601-1, and its Li-ion battery complies with the battery safety standard IEC 62133-2, so the difference in battery capacity would not affect its safety and effectiveness.

Difference (5)

The proposed device includes the same main specifications as compared to the predicate device but Means of input in appearance, which is caused by different appearance design and could not effects the performance and safety.

Difference (6)

Differences in color at the reference position do not affect the performance of the product.

Difference (7)

Both the Patient contacting components materials of proposed device and predicate device meet the ISO10993-5 & ISO10993-10 standards, and the proposed device also meets the ISO10993-11 standard, the difference would not affect its safety and effectiveness.

8. 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
- Software Validation
- Electromagnetic compatibility and electrical safety
- Function test

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

9. Clinical Tests Performed

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

10. 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.