April 8, 2026

Changzhou Sifary Medical Technology Co., Ltd.
Jie Zhu
RA Manager
No. 26 Yandanghe Road, Xinbei District
Changzhou, Jiangsu 213000
China

Re: K252224
Trade/Device Name: Apex Locator (FindPex)
Regulatory Class: Unclassified
Product Code: LQY
Dated: July 16, 2025
Received: March 10, 2026

Dear Jie Zhu:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

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

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.	K252224

Please provide the device trade name(s).

Apex Locator (FindPex)

Please provide your Indications for Use below.

FindPex is used to detect the apex of root canal.

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)

K252224 - 510(k) Summary

Prepared Date: 2026.04.07

1. Submission Sponsor

Applicant: Changzhou Sifary Medical Technology Co., Ltd.
Address: No. 26 Yandanghe Road, Xinbei District, 213000 Changzhou, Jiangsu, China
Contact Person: Jie Zhu
E-mail: amanda@sifary.com
Tel: +86-152-95053964

2. Subject Device

Name of Device:	Apex Locator (model: FindPex)
Common or Usual Name:	Apex Locator
Classification Name:	Locator, Root Apex
Regulatory Class:	Unclassified
Product Code:	LQY

3. Predicate Device

Trade Name:	Apex Locator, DPEX III
Manufacturer:	Guilin Woodpecker Medical Instrument Co., Ltd.
Predicate Submission Number:	K181087
Classification Name:	Locator, Root Apex
Regulatory Number:	Unclassified
Product Code:	LQY

4. Device Description

The apex locator is a device used in dentistry to detect the apex of the root canal. Its principle of operation relies on measuring the electrical impedance of dental tissue, which varies according to tissue density and composition. The Apex Locator (model: FindPex) consists of Apex Locator, Base, Touch Probe, File Clip, Lip Hook, Measuring Wire, Adapter and Tester.

5. Indications for Use

FindPex is used to detect the apex of root canal.

6. Comparison to the Predicate Device

The comparison between the overall specifications of predicate device (Apex Locator, DPEX III) and the new device (Apex Locator (model: FindPex)) is shown in the following table.

Parameter	Subject Device	Predicate Device
Device Trade Name	Apex Locator (Model: FindPex)	Apex Locator, DPEX III
510K Applicant	Changzhou Sifary Medical Technology Co., Ltd.	Guilin Woodpecker Medical Instrument Co., Ltd.
510(K) Number	K252224	K181087
Regulation Number	Unclassified	Unclassified
Product Code	LQY	LQY
Classification Name	Root Apex Locator	Root Apex Locator
OTC or Prescription	Prescription Use	Prescription Use
Medical Specialty	Dental	Dental

Indications for Use	FindPex is used to detect the apex of root canal.	Apex Locator, DPEX III is a micro-processor- controlled device used for locating the apex of root canal.
Electrical Power	Rechargeable lithium ion battery (3.7V)	Rechargeable lithium battery (3.7V)
Adapter	Input: AC 100-240 V, 50/60Hz, 0.2A Output: DC 5V/1A	Input: AC 100-240 V, 50/60Hz, 0.2A Output: DC 5V/1A
Display	3.5" Color TFT with IPS technology	Custom colorized 4.5" LCD
Measuring Voltage	30mVAC	Nominal – doesn't exceed 200mV AC
Frequencies used for measurements	500Hz & 8kHz	400Hz & 8kHz
Method of calculation	The ratio of impedance at two frequencies	The ratio of impedance at two frequencies
Accessory	Measuring Wire, File Clip, Lip Hook, Touch Probe, Adapter, Tester, Base	Measuring wire, File clip, Lip hook, Touch probe, Adapter, Tester
Weight	250.9g	385g
Operating Environment	Hospital environments, clinics or dental offices by qualified dental personnel	Hospital environment, clinics or dental offices by qualified dental personnel.
Button	Three push buttons: 1. Decrease key ＜ 2. Power key ⏻ 3. Increase key ＞	Three push buttons: 1. ON/OFF 2. Sound adjustment 3. Demonstration function
Sound Indication	Piezo transducer with sound level control (high, medium, low, mute)	Piezo transducer with sound level control (high, medium, low, mute)
Automatic Turn off function	The Auto Power Off can be adjusted by operator from 5min to 15min.	The device turns off automatically after 5 minutes of the idle state.
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1

In conclusion, the comparison of indications for use and technological characteristics, combined with software documentation, biocompatibility evaluation reports, reprocessing validation reports, service life verification report, EMC and electrical safety testing and performance test reports, show that the subject device to be at least as safe and effective as the predicate, and, furthermore, warrant a finding of substantial equivalence between the Apex Locator (Model: FindPex) and the predicate Apex Locator, DPEX III.

7. Summary of Non-clinical Data

The following non-clinical data were provided in support of the substantial equivalence determination.

Performance Testing:

Non-clinical performance testing was conducted on the subject device to verify that it meets applicable design input requirements and performs as intended. The performance testing of the subject device included: Positioning Accuracy Test, Apical Foramen Identification Test, Plug and Unplug Test, Tester Function Test, and Appearance and Structural Verification Test. These tests were designed to confirm that the device meets predefined acceptance criteria and functional performance specifications established during the design and development process.

In addition, a comparative performance evaluation on the root canal length measurement accuracy was conducted between the subject device and the predicate device, using the same test method and under equivalent conditions. The results demonstrated that the performance of the subject device is substantially equivalent to that of the predicate device.

Biocompatibility Testing:

During the clinical use, the Touch Probe will contact with the patient's mucosal membrane while the File Clip and

Lip Hook will contact with the patient's mucosal membrane and intact skin.
The biocompatibility evaluation of the Apex Locator (Model: FindPex) was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and FDA Recognized Consensus Standards ISO 7405:2018 "Dentistry - Evaluation of biocompatibility of medical devices used in dentistry". The battery of testing included the following tests:
• Cytotoxicity (ISO 10993-5:2009 & 6.2 and 6.3 of ISO 7405:2018)
• Sensitization (ISO 10993-10:2021)
• Irritation (Oral mucosa) (ISO 10993-23:2021)
Testing concluded that the test articles did not have a cytotoxicity effect, did not elicit sensitization reactions and oral mucosa irritation reactions.

Electrical Safety and Electromagnetic Compatibility Testing:
The product has been tested to IEC 60601-1-2:2020, IEC TR 60601-4-2:2016, IEC 80601-2-60:2019, IEC 60601-1:2020 and ANSI AAMI ES60601-1:2005/(R) 2012 & A1:2012, C1:2009/(R) 2012 & A2:2010/(R)2012 [Incl. AMD2:2021], and meets the requirements for Electrical Safety and Electromagnetic Compatibility. The test reports are included in this submission.

Software Verification and Validation Testing:
Software verification and validation testing were conducted as recommended in IEC 62304:2006+A1:2015 Medical device software - Software life cycle processes and FDA's Guidance Document "Content of Premarket Submissions for Device Software Functions". The software documentation level for this device was considered as Basic Documentation Level, since a failure or flaw of software function could not present a hazardous situation with a probable risk of death or serious injury, either to a patient, user of the device, or others in the environment of use.

8. Summary of Non-clinical Data
There were no clinical tests performed for the Apex Locator (Model: FindPex) device.

9. Conclusions
Based on the information provided in this premarket notification, Changzhou Sifary Medical Technology Co., Ltd., concludes that Apex Locator (model: FindPex) is substantially equivalent to predicate device as described herein.