January 17, 2025

Shenzhen Superline Technology Co., Ltd.
℅ Daguang Sun
Consultant
PureID Medical Technology Co., Ltd.
33/F, Bd.A, Guanzhou Life Science Innovation Center,
Guangzhou International Bio-Island, Huangpu District
Guangzhou, Guangdong 510300
China

Re: K242765
Trade/Device Name: Electronic Apex Locator (Alpha Apex I)
Regulatory Class: Unclassified
Product Code: LQY
Dated: September 1, 2024
Received: September 13, 2024

Dear Daguang Sun:

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,

Bobak Shirmohammadi -S

For 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242765

Device Name

Electronic Apex Locator (Alpha Apex I)

Indications for Use *(Describe)*

The Electronic Apex Locator is used to support the dentist in the determination of the working length during the endodontic treatment. The use of this product is intended exclusively for duly qualified dental practitioners.

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 K242765

Date Prepared: 2024.09.01

I. Submitter

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Taoyuan Street, Nanshan District, Shenzhen, 518000 Guangdong, P.R.China
Tel: +86 7552601605
Contact Person: Jinsong Zhou, Mr.

II. Device Information

Trade Name: Electronic Apex Locator (Alpha Apex I)
Common Name: Root Apex Locator
Classification: Unclassified
Product Code: LQY

III. Predicate and Reference Devices

Primary Predicate: Apex Locator (AL-Pex+)
510(k) number: K232717
Common Name: Root Apex Locator
Classification: Unclassified
Product Code: LQY

IV. Indications for Use

The Electronic Apex Locator is used to support the dentist in the determination of the working length during the endodontic treatment. The use of this product is intended exclusively for duly qualified dental practitioners.

V. Device Description

The Electronic Apex Locator is a microprocessor-controlled device used for root canal length determination. The Electronic Apex Locator assesses the electrical resistance of the tooth and surrounding tissues while the file is inserted and moving along the root canal. By detecting the change of the impedance value of the tooth apex to the AC current response of two different frequencies, two signals are output that are proportional to the change of the AC current response of two different frequencies corresponding to the tooth apex, and the two response signals are compared, and the digital quantity of their ratio is output. The digital quantity represents the position of the electrode at the tooth apex.

Advanced user interface implemented in Electronic Apex Locator is based on high resolution TFT (Thin Film Transistor) color graphic display. It provides presentation of endodontic file movement inside the canal. In addition, the interface displays the mute or volume level and power status.

The product is functionally operated by three buttons: 1) On/off button of the main unit: Short press once to hear a beep is to start up the machine, short press once again to shut down, and long press no

response. 2) Volume button: Under the startup state, press once to increase one volume. After reaching the maximum volume, press once to enter the mute mode. Press four times as a cycle, and there will be no responds when long press. 3) DEMO button: Under the startup state, long press to enter the DEMO process, and the screen will demonstrate the process of measuring the length.

VI. Technological Comparison

The following Table 1 provides a summary of the subject Electronic Apex Locator features compared to the predicate device, Apex Locator (AL-Pex+) (K232717).

Table 1 – Comparison Table of the Subject Device and Predicate Device

Attribute	Subject: Electronic Apex Locator	Predicate: Apex Locator (AL-Pex+) (K232717)	Similarities/ Differences
Product Code	LQY	LQY	Same
Regulatory Class	Unclassified	Unclassified	Same
Regulation Number	Unclassified	Unclassified	Same
Intended Use	The Electronic Apex Locator is used to support the dentist in the determination of the working length during the endodontic treatment. The use of this product is intended exclusively for duly qualified dental practitioners.	support the dentist in the determination of the working length during the endodontic treatment. The use of this product is intended exclusively for duly qualified dental practitioners.	Same
Dimension	Length: 122 mm Width: 112 mm Thickness: 23 mm	Length: 116 mm Width: 67 mm Height: 20 mm	Similar. The subject device and the predicate device have different appearances; however, this does not affect the safety or substantial equivalence of the devices.
Cable length	Measurement cable:1.6m File clip cable: 0.2m	Measurement cable A:1.5m File clip cable:0.2m	Similar. These cables are for the same function with different

			lengths and different names.
Weight	285 g	188g	Similar. The subject devices and the predicate device are with different weight; however, this does not affect the safety or substantial equivalence of the devices.
Measurement Accuracy	±0.5mm	±0.5mm	Same
Patient contacting components materials	Lip hook: 304 stainless steel	Lip hook: Stainless Steel; File Clip: Stainless Steel, Nylon and Silicone; Probe: Stainless Steel and Silicone	Similar. The patient contacting components are all proved to be biocompatible.
Power supply	Lithium battery DC3.7V, 800 mAh	Rechargeable Li-ion battery Capacity 1000 mAh,3.7V	Different. The battery capacity is different. The battery of subject device meets standard IEC 62133-2 which proved its safety and effectiveness.
Battery Charger	Input: AC100V ~ 240V 50/60Hz, 0.5A Max; Output: DC5V, 2A; Class II equipment during charging	Input:100-240V AC 50/60Hz 0.2 A output: DC 5V 1A	Similar. The battery charger of subject device meets IEC 60601-1 standard and the slight difference does not affect the safety or substantial equivalence.
Bluetooth	No Bluetooth function	No Bluetooth function	Same
Display	5.1” TFT color graphic display	3.5” TFT LCD	Similar. The subject devices and the predicate device are with different size of display; however, this does not affect the safety or substantial

			equivalence of the devices.
Sterilization	Lip hook, file holder and touch probe are user sterilized by steam sterilization	Lip hook, File clip and Probe are user sterilized by steam sterilization	Same
Biocompatibility	ISO 10993-5 ISO 10993- 10 ISO 10993- 23	ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-23:2021	Same
Electrical Safety	IEC 60601-1:2005 + AMD1.2012 + AMD2:2020; IEC 80601-2-60: 2019	AAMI ES60601-1:2005+AMD1:2012+AMD 2:2021 IEC 60601-1:2005, AMD1:2012,AMD2:2020; IEC 80601-2-60:2019	Same
EMC	IEC 60601-1-2:2014+A1:2020, EN 60601-1-2:2015+ A1:2021	IEC 60601-1-2:2014+AMD:2020	Same

Comparison Analysis:

The information in this submission established that the Electronic Apex Locator has the same intended use and similar technological characteristics as the predicate device. All performance testing met acceptance criteria. Therefore, the Subject Device is substantially equivalent to the predicate device.

VII. Biocompatibility

The biocompatibility evaluation for the device was conducted in accordance with 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". The biocompatibility testing includes the following tests:

- Cytotoxicity in accordance with ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
- Sensitization in accordance with ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.
- Irritation in accordance with ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation.

VIII. Cleaning & Sterilization Validation

Cleaning, Disinfection and Sterilization Validation of subject device has been conducted in accordance with:

- Guidance for Industry and Food and Drug Administration Staff: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.
- AAMI TIR30:2011/R2016: A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- ISO 11737-1:2018/Amd1:2021: Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
- ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 17665-2:2009 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1

IX. EMC and Electrical Safety Testing

Testing including electrical safety, mechanical safety, thermal safety, EMC and performance have been conducted to the subject device in accordance with the following standards and the device has demonstrated safety and good performance under normal operating conditions:

- IEC 60601-1:2005 + AMD1.2012 + AMD2:2020 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020, EN 60601-1-2:2015+ A1:2021 Medical electrical equipment -Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: ELECTROMAGNETIC disturbances-Requirements and tests
- IEC 80601-2-60: 2019 for use in conjunction with IEC 60601-1:2005, COR1:2006, COR 2:2007, AMD1:2012 Medical electrical equipment Part 2: Particular requirements for basic safety and essential performance of dental equipment.
- IEC 60601-4-2:2016 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

X. Performance Testing

Accuracy Testing:

The following testing has been fully conducted to ensure that the subject device functions as intended and substantially equivalent to predicate device: Performance testing to verify the apex position measurement accuracy according to internal technical requirements has been conducted and demonstrated that the subject device meets the requirement of ±0.5mm, which is the same as the predicate device and therefore verified the subject device's substantial equivalence compared with the predicate device.

Software Verification and Validation:

The software Alpha Apex I.1.0.0 applied to the subject device, Electronic Apex Locator, has been verified and validated in accordance with FDA software validation guidance: “General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002". Software documentation for moderate level of concern per the FDA Guidance Document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”.

XI. Clinical Testing

No clinical testing was required for the determination of substantial equivalence and therefore no such testing was conducted.

XII.Conclusion

The validations and testing have demonstrated that the subject device Electronic Apex Locator is substantially equivalent to its predicate device when used as intended.