December 22, 2023

Changzhou Haili Medical Co., Ltd.
Wang Xiaofang
Quality manager
Hutang Science Technology Industrial Park,
Wujin District
Changzhou, Jiangsu 213000
CHINA

Re: K232717
Trade/Device Name: Apex Locator (AL-Pex), Apex Locator (AL-Pex+)
Regulatory Class: Unclassified
Product Code: LQY
Dated: November 22, 2023
Received: November 22, 2023

Dear Wang Xiaofang:

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.

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.

Submission Number *(if known)*

K232717

Device Name

Apex Locator (AL-Pex);
Apex Locator (AL-Pex+)

Indications for Use *(Describe)*

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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K232717

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: November 20, 2023

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Changzhou Haili Medical Co., Ltd.
Address:	Hutang Science Technology Industrial Park, Wujin District, Changzhou, Jiangsu, 213000 China
Contact person:	Wang Xiaofang
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2. Device Identification

510(K) number:	K232717
Trade/Device Name:	Apex Locator (Model: AL-Pex, AL-Pex+)
Common name:	Locator, Root Apex
Regulation Number:	N/A
Regulation Name:	Locator, Root Apex
Regulation Class:	Unclassified
Panel:	Dental
Product Code:	LQY

3. Predicate Device

510(K) number:	K203836 (Primary predicate)
Device Name:	BOMEDENT Apex locator (Model: iRoot apex)
Manufacturer:	ChangZhou BoMedent Medical Technology Co.,Ltd
Common name	Locator, Root Apex
Regulation Number:	N/A
Regulation Name:	Locator, Root Apex
Regulation Class:	Unclassified
Panel:	Dental
Product Code:	LQY

4. Device Description

Apex locators are equipment used for working length measurement during root canal treatment. The devices are powered by a built-in lithium battery, can be charged by a USB adaptor. The devices employ a LCD screen to display the status of file in the root canal and the relative distance between file tip and reference point.

The devices are reusable medical devices initially supplied as non-sterile to the user and requiring the user to clean and disinfect the surface of device. And their accessory, Dental root canal file clip, Dental lip hook and probe are reusable, initially supplied as non-sterile to the user, and requiring the user to sterile for initial use, as well as to reprocess after each use.

The devices include a main unit, a measurement wire A, a measurement wire B, a dental root canal file clip, a dental lip hook, a probe and an adaptor.

Main unit: measure and display working length.

Measurement wire A: connect file clip and lip hook with main unit.

Measurement wire B: connect lip hook and main unit with EM-Motor root canal preparation device.(The EM-Motor root canal preparation device is not included with the subject device and is sold separately.)

File clip: Connect to file.

Lip hook: hook patient's lip.

Touch Probe: promote to measure molar.

Power Adapter: use for charging.

Tester: use for checking whether the device is normal.

5. Indication for use

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.

6. Summary of the device compared to the predicate device

Compared to the predicate device, the subject device has the same intended use, similar product design, same performance effectiveness, performance safety as the predicate device, summarized comparison information is listed in the following table:

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SE Comparisons	Subject Devices K232717		Predicate Device K203836 BOMEDENT Apex locator	Similarities/Differences
	Apex locator (Model: AL-Pex)	**Apex locator** (Model: AL-Pex+)		
Indication for Use	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.	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
Dimensions	Length: 116 mm Width: 67 mm Height: 20 mm	Length: 116 mm Width: 67 mm Height: 20 mm	Length: 110 mm Width: 65 mm Height: 20 mm	The subject devices and the predicate device are different appearance, however, this do not affect the safety or substantial equivalence.
Cable length	Measurement cable A:1.5m Measurement cable B:1.5m File clip cable:0.2m		Charger cable:1.1m Measurement cables:1.6 m File clip cable: 0.2 m	These cables are same function with different length.
Weight	182g	188g	185g	The subject devices and the predicate device are different weight, however, this do not affect the safety or substantial equivalence.
Accuracy	±0.5mm		±0.5mm	Same
Patient contacting components	Lip hook: Stainless Steel		Lip hook: Stainless Steel	Same
	File Clip: Stainless Steel, Nylon and Silicone		File Clip: Silicone and stainless steel	Materials of File Clip are different. File Clip of the

material composition Material			subject device meets biocompatibility requirements.
	Probe: Stainless Steel and Silicone	N/A	Probe of the subject device meets biocompatibility requirements.
Power supply	Rechargeable Li-ion battery Capacity 1000 mAh,3.7V	Rechargeable Li-ion battery Capacity 950mAh,3.7V	The battery capacity is different. The battery of subject device meet standard UL1642:2012 and IEC 62133-2.
Battery Charger	Input:100-240V AC 50/60Hz 0.2 A output: DC 5V 1A	Input:100-240V AC 50-60Hz 0.15 A output:DC 5V 1A	The input current is different. The battery charger meet IEC 60601-1 ANSI/AAMI ES60601-1 CSA CAN/CSA-C22.2 NO. 60601-1:14 standard, this do not affect the safety or substantial equivalence.
Bluetooth	No Bluetooth function	No Bluetooth function	Same
Display	3.5'' TFT LCD	3.5'' TFT Wide angle of view LCD	Same
Reference point	In the menu of Ref Point, the reference point can be adjusted from 0.0 – 2.0	In the menu of Ref Point, the reference point can be adjusted from 0.0 – 1.2.	the reference point can be adjusted by user (dentist). This do not affect the safety or substantial equivalence.
Sterilization	Lip hook, File clip and Probe are user sterilized by steam sterilization	Lip hook and File clip are user sterilized by	The subject devices include a probe, it is

		steam sterilization	required sterilization, sterilization validation were conducted.
Electrical Safety	AAMI ES60601-1:2005+AMD1:2012+AMD2:2021 IEC 60601-1:2005,AMD1:2012,AMD2:2020 IEC 80601-2-60:2019	IEC 60601-1:2012 IEC 80601-2-60:2019	The standards were updated, we conducted the tests according to new version.
EMC	IEC 60601-1-2:2014+AMD:2020	IEC 60601-1-2:2014	The standards were updated, we conducted the tests according to new version.
Biocompatibility	ISO 10993-5:2009 ISO 10993-10:2021 ISO 10993-11:2021	ISO 10993-5:2009 ISO 10993-10:2010	The standards were updated, we conducted the tests according to new version.

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The subject devices Apex Locator (Model: AL-Pex, AL-Pex+) comply with:

Safety and performance:

1. AAMI ES60601-1:2005+AMD1:2012+AMD2:2021 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

IEC 60601-1:2005,AMD1:2012,AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

2. IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

Electromagnetic Compatibility:

3. IEC 60601-1-2:2014+AMD1:2020 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests

Biocompatibility:

4. ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
5. ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
6. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Accuracy verification

7. Internal method

Software Verification and Validation:

8. FDA software validation guidance “General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002”.
9. 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

Reprocess

10. Cleaning, Low Level Disinfection, and Sterilization validation of the components of the subject device per the FDA Guidance Document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,

11. AAMI TIR 12:2020 Designing, testing, andlabeling medical devicesintended for processingby health care facilities:A guide for device manufacturers

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device.