February 13, 2024

Cefla S.C.
Daidone Simona
Regulatory Affairs
Via Selice Provinciale N.23/A
Imola, Bologna 40026
ITALY

Re: K231990
Trade/Device Name: Apex Locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: January 17, 2024
Received: January 17, 2024

Dear Daidone Simona:

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.

510(k) Number *(if known)*
K231990

Device Name
APEX LOCATOR

Indications for Use *(Describe)*
APEX LOCATOR is a device intended for locating the apex of the root canal during endodontic treatments.

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."

K231990

510(k) SUMMARY, AS REQUIRED BY CFR 807.92

Submitter's Name:	CEFLA S.C.
Address:	Via Selice Provinciale 23/a Imola, BO 40026 ITALY Tel. +39 0542 653111 Fax +39 0542 653444
Establishment Registration Number:	3006610845
Summary Preparation Date:	February, 12th,2024
Contact Person:	Simona Daidone, Regulatory Affairs
Telephone Number:	+39 0542 653441
Email:	regulatory@cefla.it
Trade/Device name:	Apex Locator
Common or Usual Name:	Dental Root Apex Locator
Classification Name:	Classification Name: Unclassified Device Class: Unclassified Product Code: LQY
Description:	APEX LOCATOR is a device used in dentistry to estimate the position of the root apex of teeth during root canal preparation. It is used connected with the Cefla dental units. Its principle of operation relies on measuring the electrical impedance of dental tissue, which varies according to tissue density and composition. The APEX LOCATOR is an accessory device for the Cefla dental units used to estimate the position of the root apex of teeth during root canal preparation. The kit is composed of the following elements: • touch probe (2 pieces)

- file clip (2 pieces)
- lip hook (4 piece)
- external wiring (1 piece)

Indication for Use: APEX LOCATOR is a device intended for locating the apex of the root canal during endodontic treatments.

Identification of Predicate Device:

CEFLA S.C. will refer to the following predicate device (1):

Proprietary Name: Guilin Woodpecker Medical Instrument
Classification Name: Unclassified
Registered Establishment Name: 3005581016
Guilin Woodpecker Medical Instrument Co., Ltd.
Information Industrial Park, Guilin National High-Tech Zone
Guilin City, CN 541004Owner/Operator: W&H
Establishment Operations: Manufacturer
510 (k): K181087
Device Name: APEX LOCATOR DPEX III
Applicant: Guilin Woodpecker Medical Instrument

Comparison of technological characteristics with the predicate and reference devices:

Characteristics	**Subject Device**	**Predicate Device**
Device Trade Name	Apex Locator	Apex Locator, DPEX III
510K Applicant	Cefla S.C.	GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD
510(K) Number	-	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	APEX LOCATOR is a device intended for locating the apex of the root canal during endodontic treatments.	DPEX III is a microprocessor-controlled device used for locating the apex of root canal.
Electrical Power	Dental Unit power supply	Rechargeable lithium battery(3.7V)
Adapter	Not applicable	Input: AC100-240V 50/60Hz Output: DC5V 1A
Display	On the dental unit	Custom colorized 4.5” LCD

Measuring Voltage	Nominal – doesn't exceed 200mV AC	Nominal – doesn't exceed 200mV AC
Frequencies used for measurements	400Hz & 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	Measuring wire, File clip, Lip hook, Touch probe, Adapter, Tester
Operating Environment	Hospital environment, clinics or dental offices by qualified dental personnel	Hospital environment, clinics or dental offices by qualified dental personnel
Button	On the dental unit	Three push buttons: 1. ON/OFF 2. Sound adjustment 3. Demonstration function
Sound Indication	On the dental unit	Piezo transducer with sound level control (high, medium, low, mute)
Automatic Turn off function	Not present	The device turns off automatically after 5 minutes of the idle state.
Calibration	Not required	Not required
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1

Non-clinical Performance Testing:
Electrical safety Test was conducted and performed in accordance with IEC 60601-1.
Electromagnetic compatibility Test was conducted and performed in accordance with IEC 60601-1-2.
Usability test was conducted in accordance to IEC 60601-1-6.
Basic level software documentation per Content of Premarket Submissions for Device Software Functions
Evaluation of biocompatibility is based on:
ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and Testing";
Validation of the reprocessing according "FDA guidance Reprocessing Medical Devices Health Care Settings: Validation Methods and Labeling. "
Performance tests have been performed according to internal protocol and method.

Clinical Testing: Clinical performance testing was not conducted.

Conclusion: CEFLA S.C. considers the Apex Locator to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in intended use, principle of operation, functional design, and established medical use. Differences between the devices shown in the comparison section above are minor and do not have any negative effect on substantial equivalence.