Guilin Woodpecker Medical Instrument Co., Ltd.
% Charlie Mack
Principal Engineer
Irc
2950 E Lindrick Drive
Chandler, Arizona 85249

December 18, 2018

Re: K181087
Trade/Device Name: Apex Locator, DPEX III
Regulatory Class: Unclassified
Product Code: LQY
Dated: September 8, 2018
Received: September 19, 2018

Dear Charlie Mack:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2018.12.18 15:05:16 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181087

Device Name
Apex Locator, DPEX III

Indications for Use *(Describe)*
Apex Locator, DPEX III is a microprocessor controlled device intended for locating the apex of root canal.

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.

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Guilin Woodpecker Medical Instrument Co., Ltd.

510(k) Summary (21 CFR §807.92)
510(k) assigned number K181087

Submitter Information:

Submitter Name: Guilin Woodpecker Medical Instrument Co., Ltd.
Address: Information Industrial Park, Guilin National High-Tech Zone, Guilin City, Guangxi Province, P.R. China 541004

Contact Person: Mr. Xunxian Wu
President
charliemack@irc-us.com
931-625-4938

Date of Preparation: December 15, 2018

Subject Device	Trade Name:	Apex Locator, DPEX III
	Common Name:	Root apex locator
	Regulation Number:	Pre-Amendment
	Regulation Name:	locator, root apex
	Regulatory Class:	Unclassified
	Product Code:	LQY
	Classification Panel:	Dental

Primary Predicate Device

Trade Name:	RAYPEX 6
510(k) Reference:	K131907
Common Name:	Root apex locator
Regulation Number:	Pre-Amendment
Regulation Name:	locator, root apex
Regulatory Class:	Unclassified
Product Code:	LQY
Classification Panel:	Dental

Purpose of Submission

This is a new submission of an apex root locator.

Device Description

Apex Locator, DPEX III is an apex locator intended for precise localization of root canal apex.
Operation of Apex Locator, DPEX III is fully automatic, no manual calibrations or adjustments are required. The measuring signal is analyzed, and automatic adjustments are made if needed. The device may operate within different conditions in the root canal. Apex Locator, DPEX III may only be used with stainless steel or nickel titanium endodontic files. The scale indication on the apex locator screen does not represent a distinct length or distance in mm or other linear units. It merely indicates the file progression towards the apex.

Indications for Use

Apex Locator, DPEX III is a microprocessor- controlled device used for locating the apex of root canal.

SUBJECT *Indications for Use*	PRIMARY PREDICATE Device (K131907) *Indications for Use*
Apex Locator, DPEX III is a microprocessor-controlled device used for locating the apex of root canal.	Rapex 6 is a microprocessor-controlled device used for locating the apex.

All the labeling and characteristics of the submitted Apex Locator, DPEX III is the same as the primary predicate device and most typical apex locators currently on the market. The submitted device and predicate both are used in routine procedures.

The basic design of the submitted device specifications is substantially the same as the predicate, with differences in the display, weight, and frequencies used for measurements. Testing validates that the performance of the Apex Locator, DPEX III is comparable to the predicate device.
Sterilization validation and performance testing has verified that the submitted device is safe for use.

Technological Characteristics

Technological characteristics of the subject and predicate devices are equivalent. The subject device Apex Locator, DPEX III achieves its intended use based on the same technology and principles of operation as the predicate device, Rapex 6 apex locator.

Characteristics	Subject Device	Primary Predicate Device
Device Trade Name	Apex Locator, DPEX III	Apex Locator, RAYPEX 6
510K Applicant	GUILIN WOODPECKER MEDICAL INSTRUMENT CO., LTD	DENTSPLY International
510(K) Number	K181087	K131907
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	DPEX III is a microprocessor-controlled device used for locating the apex of root canal.	RAYPEX 6 is a microprocessor-controlled device used for locating the apex.
Electrical Power	Rechargeable lithium battery(3.7V)	Rechargeable NiMH batteries(2.4V)
Adapter	Input: AC100-240V 50/60Hz Output: DC5V 1A	Input: AC100-240V 50/60Hz Output: DC5V 1A
Display	Custom colorized 4.5” LCD	3.5” colorized TFT
Measuring Voltage	Nominal – doesn’t exceed 200mV AC	Nominal – doesn’t exceed 200mV AC
Frequencies used for measurements	400Hz & 8kHz	500Hz & 8kHz
Method of calculation	The ratio of impedance at two frequencies	The ratio of impedance at two frequencies

Characteristics	Subject Device	Primary Predicate Device
Accessory	Measuring wire, File clip, Lip hook, Touch probe, Adapter, Tester	Measuring wire, File clip, Lip hook, Touch probe, Adapter, Tester
Weight	385g	350g
Operating Environment	Hospital environment, clinics or dental offices by qualified dental personnel.	Hospital environment, clinics or dental offices by qualified dental personnel
Button	Three push buttons: 1. ON/OFF 2. Sound adjustment 3. Demonstration function	One push button: ON/OFF -Touchscreen
Sound Indication	Piezo transducer with sound level control (high, medium, low, mute)	A speaker which enables: -the sound level adjustment from mute to the high sound level -tone selection
Automatic Turn off function	The device turns off automatically after 5 minutes of the idle state.	The device turns off automatically after 5 minutes of an idle state.
Calibration	Not required	Not required
Biocompatibility	Complies with ISO10993-1	Complies with ISO10993-1

The submitted Apex Locator DPEX III uses the same technology to determine the apex of the root, using two frequencies that are alternated, with the ratios of the impedance measurement to determine the apex of the root canal. Both the subject device and the predicate Rapex 6 use a sound alert when the file is near the apex. The Apex Locator DPEX III uses a different high frequency, but testing reveals that there is no performance difference between the predicate and submitted device.

Summary of Performance Tests

The following performance testing was performed to demonstrate substantial equivalence of the subject device Apex Locator DPEX III and applicable standards:

Non-clinical Test

Performance Comparison Test:

The comparison testing on Apex Locator, DPEX III and the predicate device (RAYPEX 6 (K131907) was performed to compare the measurement performance of locating apex root using extracted tooth. The result obtained with the Apex Locator, DPEX III is clinically acceptable since they are equivalent to the results of the predicate device.

Safety and EMC Test:

1. IEC 60601-1: 2005+CORR.1 (2006)+CORR.2(2007)+AM1(2012) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2: 2014 Medical devices part 1-2: General requirements for basic safety and essential performance – Collateral standards: electromagnetic compatibility – Test and requirements

The safety and EMC testing confirm that the subject device complies with the same FDA recognized safety and EMC standards as the primary predicate device. All of the pre-determined acceptance criteria were met.

Biocompatibility Test:

1. Cytotoxicity Tests (ISO10993-5)
2. Skin Irritation Test (ISO10993-10)
3. Oral Mucosa Irritation Test (ISO10993-10)
4. Skin Sensitization Test (ISO10993-10)

The test result shows that the subject device complies with the same FDA recognized biocompatibility standards as predict device. All of the pre-determined acceptance criteria were met.

Sterilization Validation:

1. 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 (Sterility)
2. ISO 11737-2:2009, Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the validation of a sterilization process. (Sterility)
3. ANSI AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

The steam sterilization validation study supports the labeling of sterilization method for the accessories subject to be sterilized at the clinical site.
All of the pre-determined acceptance criteria were met.

Clinical Test

No clinical study is included in this submission.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and performance testing, the subject Apex Locator, DPEX III has demonstrated to be substantially equivalent to the primary predicate Rapex 6 Apex Locator.

END
