July 20, 2022

Foshan COXO Medical Instrument Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5 YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
China

Re: K212178
Trade/Device Name: Root Apex Locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: June 14, 2022
Received: June 21, 2022

Dear Ray Wang:

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/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 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 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,

For Michael E. Adjodha, M.ChE.
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)*

K212178

Device Name
Root Apex Locator

Indications for Use *(Describe)*

The Root Apex Locator is used to detect the apex of root canal.This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

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.

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The assigned 510(k) Number: K212178

510(k) Summary

This 510(k) Summary was prepared in accordance with the requirements of Title 21, CFR Section 807.92.

1. Date of Preparation: 2022/07/14

2. Sponsor Identification

Foshan COXO Medical Instrument Co., Ltd.
BLDG 4, District A, Guangdong New Light Source Industrial Base, South of Luocun Avenue, Nanhai District, Foshan, 528226 Guangdong, China.

Contact Person: Yongjian Zheng
Position: Legal Representative
Tel: +86-13702544788
Fax: +86-757-81800058
Email: 13702544788@163.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, 102401, China

Tel: +86-18910677558
Fax: +86-10-56335780
Email: Ray.Wang@believe-med.com

4. Identification of Proposed Device

Trade Name: Root Apex Locator
Common Name: Locator, Root Apex

Regulatory Information
Classification Name: Locator, Root Apex
Classification: Unclassified
Product Code: LQY
Regulation Number: N/A
Review Panel: Dental

Indication for use Statement:

The Root Apex Locator is used to detect the apex of root canal.This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

Device Description:

The Root Apex Locator C-ROOT I is a oral equipment used for root canal measurement. The device includes a TFT colour display with touch panel displays parameters such as battery status, connection status of test wire and apex position, etc. Users can also set and modify the sound level, brightness level, DR'S CHOICE via a touch panel, and provide a functional check of the device and cable.

The Root Apex Locator is used to detect the apex of root canal.This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

The Root Apex Locator C-ROOT I is intended to be sterilized prior to use.

The material composition of root canal files that can be used with the Root Apex Locator C-ROOT I is Nickel titanium (NiTi).

5. Identification of Predicate Device(s)

Predicate Device
K203836
BOMEDENT Apex locator
ChangZhou BoMedent Medical Technology Co.,Ltd

Reference Device:
510(k) Number: K201993
Product Name: E-connect S Endo Motor with built-in Apex Locator

Manufacturer: Changzhou Sifary Medical Technology Co., Ltd.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity.
- IEC 60601-1:2012, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests
- IEC 80601-2-60 Edition 2.0 2019-06 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment;
- IEC 62133-2 Edition1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Software Verification and Validation:
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

Performance Testing:
Accuracy Testing:
Internal test method demonstrated that the apex position measurement accuracy of the proposed Root Apex Locator C-ROOT I meets the requirement of ±0.5mm, the accuracy ±0.5mm is the same as that of reference device E-connect S Endo Motor with built-in Apex Locator (K201993) .
The tests demonstrate substantial equivalence between the proposed device and the reference device.

Cleaning Disinfection Validation and Sterilization validation of the components of the proposed device according to the FDA Guidance Document-Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, AAMI TIR 12, AAMI ST 81,ISO 17665-1.

Battery Performance:

Both the proposed devices and the predicate device are powered by rechargeable 3.7V Li-ion battery, and both the Li-ion battery of the proposed device and the predicate device comply with the battery safety standard IEC 62133-2.

The IEC 62133-2 test demonstrates substantial equivalence between the proposed device and the predicate device.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

Item	Proposed Device K212178	Predicate Device K203836	Reference Device K201993	Remark
Device name	Root Apex Locator	BOMEDENT Apex locator	E-connect S Endo Motor with built-in Apex Locator	/
Classification Regulation	Unclassified	Unclassified	21CRF 872.4200	Same with the Predicate Device
Classification	Unclassified	Unclassified	Class I	Same with the Predicate Device
Product Code	LQY	LQY	EKX/LQY	SAME
Common Name	Locator, Root Apex	Locator, Root Apex	endodontic treatment motorized handpiece/ root canal apex locator	SAME
Indications for use	The Root Apex Locator is used to detect the apex of root canal.This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	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.	E-connect S is a cordless endodontic treatment motorized handpiece with root canal measuring capability. It can be used to enlarge canals while monitoring the position of the file tip inside the canal. It can be used as a low-speed motorized handpiece and device	SAME Both the proposed devices, the predicate device and the reference device have the Indications for use of detecting the apex of root canal.

			for measuring canal length.This device must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	
Dimensions	Length: 110mm Width: 103 mm Thickness: 21.5mm	Length: 110 mm Width: 65 mm Height: 20 mm	21.5cm × 17.5cm × 9cm	Difference(1)
Cable length	Charger cable: 1.5m Tester cable: 1.4m	• Charger cable: 1.1m • Measurement cables:1.6 m • File clip cable: 0.2 m	/	Difference(2)
Weight	270g	185g	/	Difference(3)
Power supply	Li-ion Battery DC 3.7V 1800mAh	Rechargeable Li-ion battery Capacity 950mAh,3.7V	Li-ion battery (DC 3.7V)	Difference(4)
Charger	Input: AC 100-240 V, 50/60 Hz Output: DC 5V 1A Classification of Protection against Electric Shock：Class II (adaptor)	• Power supply:100 - 240 VAC • Frequency:50 - 60 Hz • Nominal power output:0.15A • Electrical safety class:Class II	/	Same with the Predicate Device Same safety level.
Means of input	• Touch screen • Foldable main unit	• Touch screen • Foldable main unit	/	Same with the Predicate Device
Display	3.5'' TFT colour display	3.5'' TFT Wide angle of view LCD	/	Same with the Predicate Device
Adjustment before measurement	The DR'S CHOICE Apical Arrow function enables to mark an individual predetermined reference position at the required distance from the apex. This variable apical arrow can be set between the first green bar and the last yellow bar.	In the menu of Ref Point, the reference position can be adjusted from 0.0 – 1.2.	/	Difference(5)
Measurement Accuracy	±0.5mm	/	-0.5mm to+0.5mm for Apex position	Same with the Reference Device
Patient	Lip hook: 304 Stainless	Lip Clip: Stainless	Used materials	Difference(6)

contacting components materials	steel; File clip: PI and 304 Stainless steel	Steel File Clip: Silicone and stainless steel	conform to ISO10993.	
Sterilization	Lip clip and file clip are user sterilized by steam sterilization.	Lip clip and file clip are user sterilized by steam sterilization.	Contra Angle, Lip Hook, File clip, Insulating Sleeve autoclavable.	SAME
Applied Standards:				
Biocompatibility	ISO10993-5 &ISO10993-10 &ISO10993-11	ISO10993-5 &ISO10993-10	ISO10993-5 &ISO10993-10	Difference(7)
Electrical Safety	IEC 60601-1	Conform to IEC60601-1	Conform to IEC60601-1	SAME
Mechanical safety	IEC 60601-1	Conform to IEC60601-1	Conform to IEC60601-1	SAME
Thermal safety	IEC 60601-1	Conform to IEC60601-1	Conform to IEC60601-1	SAME
EMC	IEC 60601-1-2	Conform to EN 60601-1-2	Conform to IEC 60601-1-2	SAME
Performance	IEC 80601-2-60	IEC 80601-2-60	IEC 80601-2-60 ISO 14457	Same with the Predicate Device
Material of the applicable root canal files	Nickel titanium (NiTi)	Unknown	Unknown	Difference(8)

Analysis：

Difference(1)

The proposed device includes the same main specifications as compared to the predicate device but differs in dimension, which is caused by different appearance design and could not effects the performance and safety.

Difference(2)

There is a difference in the cable length, but these cables include the same function , the cable length difference would not affect its safety and effectiveness.

Difference(3)

The proposed device and the predicate device have a different weight, however, this could not effect the performance and safety.

Difference(4)

Both the proposed device, the predicate device and the reference device are powered by rechargeable 3.7V Li-ion battery, there is a difference in the battery capacity. The proposed device compli e s with

electrical safety standard IEC 60601-1, and its Li-ion battery complies with the battery safety standard IEC 62133-2, so the difference in battery capacity would not affect its safety and effectiveness.

Difference(5)

There is a difference on the description of adjustment before measurement, however both the proposed device and the predicate device have the same function, the proposed device does not specify the specific value of the adjustment range, but uses colors to identify the adjustment range, so such description difference would not affect its safety and effectiveness .

Difference(6)&(7)

Both the Patient contacting components materials of proposed device and predicate device meet the ISO10993-5 &ISO10993-10 standards, and the proposed device also meets the ISO10993-11 standard, the difference would not affect its safety and effectiveness.

Difference(8)

The material of root canal files that can be used with the predicate device and the reference device are unknown, however, a clinical accuracy study was conducted on the proposed device and root canal file of Nickel titanium (NiTi) material, the result meet the requirement of ±0.5mm measurement accuracy, so the difference would not affect its safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.