March 30, 2021

ChangZhou BoMedent Medical Technology Co., Ltd
Zhang Lili
Quality Manager
No.9 Changyang Road,
West Taihu Science & Technology Industrial Park,
Changzhou, Jiangsu 213100
CHINA

Re: K203836
Trade/Device Name: BOMEDENT Apex locator, WISMY Apex locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: December 18, 2020
Received: December 30, 2020

Dear Zhang Lili:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental 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)*
K203836

Device Name
BOMEDENT Apex locator, WISMY Apex locator

Indications for Use *(Describe)*
BOMEDENT Apex locator and WISMY Apex locator 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.

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K203836 - 510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 18 December 2020

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	ChangZhou BoMedent Medical Technology Co.,Ltd
Address:	No.9 Changyang Road,West Taihu Science & Technology Industrial Park, Changzhou, Jiangsu China.
Contact person:	Zhang Lili
Title:	Quality Manager
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2. Device Identification

Trade/Device Name:	BOMEDENT Apex locator, WISMY Apex locator
Models:	iRoot apex, Wispex
Common name:	Locator, Root Apex
Regulation Number:	N/A
Regulation Name:	N/A
Regulation Class:	Unclassified
Panel:	Dental
Product Code:	LQY

3. Primary Predicate

510(K) number:	K191806
Device Name:	Propex IQ® Apex Locator
Manufacturer:	Dentsply Sirona
Common name	Locator, Root Apex
Regulation Number:	N/A
Regulation Name:	N/A
Regulation Class:	Unclassified
Panel:	Dental
Product Code:	LQY

4. Device Description

The proposed BOMEDENT Apex locator and WISMY Apex locator are microprocessor-controlled devices can support the dentist during endodontic treatments for the determination of the proximity of the file to the reference point for endodontic working length determination. To do so, the proposed BOMEDENT Apex locator and WISMY Apex locator assess the electrical resistance of the tooth and surrounding tissues while the file is inserted and moving along the root canal. The proposed BOMEDENT Apex locator and WISMY Apex locator products configuration consist of the following components:

① Power Adapter② USB cable③ Measuring cable A④ File clip⑤ Lip hook

⑥ Measuring cable C (Optional)

5. Indication for use

BOMEDENT Apex locator and WISMY Apex locator 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. Comparison to Predicate Device

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table

SE Comparisons	**Proposed Devices**		**Primary Predicate Device** K191806	**Similarities/Differences**
	BOMEDENT Apex locator	WISMY Apex locator		
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.	Propex IQ® Apex Locator supports 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. Both the proposed devices and the predicate device are indicated to assist in the determination of the length of the root canal space.
Dimensions	Length: 110 mm Width: 65 mm Height: 20 mm	Length: 94 mm Width: 60 mm Height: 13 mm	Length: 75 mm Width: 46 mm Height: 20 mm	the proposed devices and the predicate device are different appearance, however, this do not affect the safety or substantial equivalence.
Cable length	• Charger cable: 1.1m • Measurement cables: 1.6 m • File clip cable: 0.2 m	• Charger cable: 1.1m • Measurement cables: 1.6 m • File clip cable: 0.2 m	• Charger cable: 2 m • Propex IQ® and X-Smart IQ® Measurement cables: 1.3 m • Propex IQ® File clip FCA: 0.15 m	These cables are same function with different length.
Weight	185g	85g	80 g (0.18 lbs)	the proposed devices and the predicate device are different weight, however, this do not affect the safety or substantial equivalence.

Patient contacting components material composition Material	Lip Clip: Stainless Steel File Clip: Silicone and stainless steel	Lip Clip: Stainless Steel File Clip: Silicone and stainless steel	Lip Clip: Stainless Steel File Clip: Gold plated beryllium copper, glass filled nylon	Material of Lip Clip is same. Material of File Clip are different. File Clip of propose device meets biocompatibility and sterile verification.
Power supply	Rechargeable Li-ion battery Capacity 950mAh,3.7V	Rechargeable Li-ion battery Capacity 950mAh,3.7V	Rechargeable 2x AAA Ni-MH Batteries: Minimum capacity 750 mAh 1.2 VDC nominal; INTERNALLY POWERED DEVICE	Proposed devices powered by rechargeable Li-ion battery that meet the requirements of IEC 62133:2013
Charger	• Power supply: 100 - 240 VAC • Frequency: 50 - 60 Hz • Nominal power output: 0.15A • Electrical safety class: Class II	• Power supply: 100 - 240 VAC • Frequency: 50 - 60 Hz • Nominal power output: 0.15A • Electrical safety class: Class II	• Power supply: 100 - 240 VAC • Frequency: 50 - 60 Hz • Nominal power output: 5.5 VA • Electrical safety class: Class II	Same safety level.
Bluetooth	No Bluetooth function	No Bluetooth function	Can be connected to Endo IQ® App (K161213) via Bluetooth and have Bluetooth function to transfer the data to the Endo IQ® App	Proposed devices are without Bluetooth function
Means of input	• Touch screen • Foldable main unit	•Select key •Volume key •Power key	• On/off pushbutton • Bluetooth button • Endo IQ® App (K161213)	Proposed devices are without Bluetooth button, other means of input are similar
Display	3.5'' TFT Wide angle of view LCD	2.8" TFT Color LCD	No display on the device, only multi-color LEDs to indicate status during the working length determination.	Proposed devices' screen display the file progression along the root canal.

Adjustment before measurement	In the menu of Ref Point, the reference position can be adjusted from 0.0 – 1.2.	adjust to set position of apex reference point. The range is 0-2.	Not required	Proposed devices can adjust reference point
Calibration	Not required	Not required	Not required	Same
Sterilization	Lip clip and file clip are user sterilized by steam sterilization.	Lip clip and file clip are user sterilized by steam sterilization.	Lip clip and file clip are user sterilized by steam sterilization.	Same

8. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The proposed BOMEDENT Apex locator and WISMY Apex locator comply with:

Safety and performance:

1. IEC 60601-1:2005+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
2. IEC 80601-2-60:2012 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment

Electromagnetic Compatibility:

3. EN 60601-1-2:2015 Medical electrical equipment-Part1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances-Requirements and tests

4. IEC 62133:2012 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

Biocompatibility:

5. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
6. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

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. It shown that the performance of the proposed BOMEDENT Apex locator and WISMY Apex locator are equivalent to that of primary predicate device Propex IQ® Apex Locator (K191806) within the scope of this test.

The tests shown substantial equivalence between the subject device and the predicate.

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, AAMI TIR 30, AAMI TIR 12, ISO 17665-1, and ISO17665-2.

9. Conclusion

Information included in this premarket notification supports the substantial equivalence of the proposed BOMEDENT Apex locator and WISMY Apex locator. The proposed device has the identical intended use as the primary predicate device cleared under premarket notification K191806. The proposed BOMEDENT Apex locator and WISMY Apex locator also have similar indications for use and incorporates the same fundamental technology as the primary predicate device (K191806). Performance, safety, and software validation test data demonstrate the performance of the subject BOMEDENT Apex locator and WISMY Apex locator against its design, functional, and safety requirements. The results of the testing support a determination of substantial equivalence.