August 3, 2022

J. Morita USA, Inc.
% Keith Barritt
Attorney
Fish & Richardson P.C.
1000 Maine Ave. S.W. 9th floor, Suite 1000
Washington, District of Columbia 20024

Re: K213477
Trade/Device Name: Root ZX3
Regulation Number: 21 CFR 872.4920
Regulation Name: Dental Electrosurgical Unit And Accessories
Regulatory Class: Class II
Product Code: EKZ, LQY
Dated: July 26, 2022
Received: July 26, 2022

Dear Keith Barritt:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K213477

Device Name
ROOT ZX3

Indications for Use *(Describe)*

The Root ZX3 device is a dental device with an apex locating function and an optional electrosurgical function and is composed of the aforementioned corresponding modules.

The apex locating function of Root ZX3 device is used for root canal measurement and working length determination.

The electrosurgical function is used for the following dental procedures: gingival incision and excision, gingivoplasty, gingivectomy, hemostasis, pulpotomy, pulpotomy as an adjunct to root canal therapy, and excision of intraoral lesions. It is also used for the ablation of pulp, dental filling material (e.g. gutta-percha) and tissue in/around root canals as an adjunct to root canal therapy, after determining the tip position of the active electrode by apex location.

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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510(k) Summary
J. Morita USA Inc.
Root ZX3
Dental electrosurgical unit with Apex locator
K#213477

The following information is provided pursuant to 21 CFR 807.92.

807.92(a)(1): Submitter's Name/Address, Contact, and Preparation Date

(i) 510(k) Submitter

J. MORITA USA, INC.
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Irvine, CA 92618
Phone: (949) 581-9600
FDA Reg. No.: 2081055

(ii) 510(k) Submitter Contact

Keith A. Barritt
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(iii) Preparation Date

June 18, 2022

807.92(a)(2): Name of Device

Trade or Proprietary Name:	Root ZX3
Model Name:	RZX3
Common Name:	Root canal apex locator / Dental electrosurgical unit
Classification Name:	Locator, Root Apex / Unit, Electrosurgical, And Accessories, Dental
Primary Product Code:	LQY
Secondary Product Code:	EKZ
Classification Panel:	LQY: - EKZ: 872 Dental
Regulation:	LQY: - EKZ: 21 CFR 872.4920

807.92(a)(3): Predicate Devices

The Root ZX3 device is substantially equivalent to the predicates with regard to the FDA medical device regulations.

Predicate for an apex locator:
The primary predicate device is J. MORITA MFG. CORP.'s own ROOT ZX II (K#071190).

Predicate for a dental electrosurgical unit:
The predicate device for an electrosurgical unit is the Bonart Art-E1 Electrosurgery Unit (K#020080). The X O Odontosurge 4 (K#023672) is a reference device for the function of dental electrosurgical unit.

Reference devices for biocompatibility:
J. MORITA MFG. CORP.'s own Root ZX mini (K#090925), Air Solfy (K#043497), Tri Auto ZX2 (K#170275), PENCURE (K#063529), and Mani Files (510(k) exempt) are reference devices for biocompatibility.

The Indications for Use statements for the subject device, primary predicate, predicate, and reference devices (where applicable) appear below:

Product No.	Indication for Use
Subject Device	The Root ZX3 device is a dental device with an apex locating function and an optional electrosurgical function and is composed of the aforementioned corresponding modules. The apex locating function of Root ZX3 device is used for root canal measurement and working length determination. The electrosurgical function is used for the following dental procedures: gingival incision and excision, gingivoplasty, gingivectomy, hemostasis, pulpotomy, pulpotomy as an adjunct to

Product No.	Indication for Use
	root canal therapy, and excision of intraoral lesions. It is also used for the ablation of pulp, dental filling material (e.g. gutta-percha) and tissue in/around root canals as an adjunct to root canal therapy, after determining the tip position of the active electrode by apex location.
K#071190 Primary predicate (Apex locator)	ROOT ZX II is a dental device, composed of a "Canal Measurement Module" and "Handpiece / LED Module". The former can measure the length of the root canal. The latter can enlarge the root canal while monitoring the position of the file tip inside the canal, and can be used to polymerize (set) resinous and other materials by light from the Light Cure Handpiece head.
K#090925 (Apex locator)	Root ZX mini is a dental device, Apex Locator. It can be used to detect the apex of root canal.
K#020080 Predicate (Dental electrosurgical unit)	The Bonart Co., Ltd. ART-E1 Electrosurgery Unit is intended for use in dental electrosurgery (electrosection), electrosection/electrocoagulation, and electrocoagulation for serious bleeding.
K#023672 (Dental electrosurgical unit)	X O Odontosurge 4 is an electrosurgery unit that is intended for use in surgical procedures of dentistry. It's indications for use statement is below. The X O Odontosurge 4 is intended for use in removing soft tissue and controlling bleeding in the oral cavity in all phases of dentistry, including prosthodontics, periodontics, endodontics, pedodontics, orthodontics, oral surgery, and routine restorative dentistry.

Reference devices for biocompatibility

Product No.	Indication for Use
K#090925	Root ZX mini is a dental device, Apex Locator. It can be used to detect the apex of root canal.
K#043497	The Air Solfy is a dental air-powered handpiece scaler and tips that can remove calculus deposits from the teeth by application of an air-powered vibrating scaler tip to the teeth during dental cleaning and periodontal therapy.
K#063529	The Pencure is intended to polymerize (set) resinous dental pit and fissure sealants or dental restorative materials by light from head.
K#170275	The Tri Auto ZX2 device is a cordless endodontic treatment motorized handpiece with root canal measurement 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 for measuring canal length.
FDA establishment reg. no. 8030343	Mani-File is a dental hand instrument, 510(k) Exempt.

807.92(a)(4): Device Description

The Root ZX3 device (also referred to by its model number RZX3) is a battery-driven apex locator with an optional dental electrosurgical unit, used in the oral cavity during dental procedures. This device has two modules: the main module is an apex locator module and the other is an electrosurgical module (high frequency [HF] module). The apex locator module is the basic module to which dental electrosurgical functions can be added by connecting the HF module.

807.92(a)(5): Intended Use

-Locating the root apex.
-Electrosurgical procedures in oral cavity.

Indication for Use

The Root ZX3 device is a dental device with an apex locating function and an optional electrosurgical function and is composed of the aforementioned corresponding modules.

The apex locating function of Root ZX3 device is used for root canal measurement and working length determination.

The electrosurgical function is used for the following dental procedures: gingival incision and excision, gingivoplasty, gingivectomy, hemostasis, pulpotomy, pulpotomy as an adjunct to root canal therapy, and excision of intraoral lesions. It is also used for the ablation of pulp, dental filling material (e.g. gutta-percha) and tissue in/around root canals as an adjunct to root canal therapy, after determining the tip position of the active electrode by apex location.

807.92(a)(6): Technological Characteristics

The Root ZX3 device has substantially equivalent basic technological characteristics in terms of design and materials as predicate devices. Although its design is slightly different from the predicate devices, Root ZX3 uses the same principle as predicate devices with the same method for apex location and use of high-frequency electric energy for electrosurgical procedures.
In addition, the Root ZX3 device is battery-driven, same as the predicate device.
The technological characteristics of the Root ZX3 device and the predicate and reference devices have been compared in a tabular format in Table 1.

807.92(b)(1): Non-clinical Testing

The Root ZX3 was tested for compliance and developed in accordance with the following international standards and FDA's guidance documents below.

ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

-This standard is designed to address the biological evaluation of medical devices within a risk management process.

ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
-This testing is designed to assess the in vitro cytotoxicity of medical devices and to determine the biological response of mammalian cells in-vitro using appropriate biological parameters.

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
-This testing is designed to assess the irritation and skin sensitization of medical devices and to determine the biological response of mammalian cells in-vivo using appropriate biological parameters.

ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
-This testing is designed to assess the systemic toxicity of medical devices and to determine the biological response of mammalian cells in-vivo using appropriate biological parameters.

IEC 80601-2-60 Ed. 2.0:2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
-This testing is designed to ensure the basic safety of the dental device.

IEC 60601-1-2 Ed. 4.0:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
-This testing is designed to ensure the electromagnetic compatibility of the device when operated in its expected use environment.

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Amendment 1 (2012)
-This testing is designed to ensure the electrical safety of the device.

IEC 60601-2-2 Ed. 6.0:2017 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
- This testing is designed to ensure the electrical safety of the device, especially high-frequency electrosurgical device.

IEC 62366-1 Ed. 1.0:2015 Medical devices - Part 1: Application of usability engineering to medical devices
-This standard is designed to analyze, specify, design, verify and validate usability as it relates to safety of a medical device. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e. normal use.

IEC 60601-1-6 Ed. 3.1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
-This standard is designed to ensure reasonable device usability to minimize use errors and use-associated risks.

ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
-This standard identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices.

ISO 14971:2007 Medical devices — Application of risk management to medical devices
-This standard provides a framework for systematically managing the risks associated with the use of medical devices. It addresses processes for managing risks, primarily to the patient, but also to the operator, other persons, other equipment, and the environment.

IEC 62304 Ed. 1.1:2015 Medical device software — Software life cycle processes
-This testing is designed to ensure the software fulfils its intended purpose without causing any unacceptable risks.

ISO 17664:2017 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
-This standard specifies the information to be provided by a medical device manufacturer on the processing of medical devices claimed to be re-sterilizable, and medical devices intended to be sterilized by the processor, so that the medical device can be processed safely and will continue to meet its performance specification. The sterility assurance level for sterilization method was 10^{-6}.

FDA's guidance document: Format for Traditional and Abbreviated 510(k)s (September 13, 2019)

FDA's guidance document: Refuse to Accept Policy for 510(k)s (September 13, 2019.)

FDA's guidance document: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (March 17, 2015)

FDA's guidance document: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005)

FDA's guidance document: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2, 2014)

FDA's guidance document: Radio Frequency Wireless Technology in Medical Devices (August 14, 2013)

A performance test was conducted to confirm that Root ZX3 can locate the apex using the method that is substantially equivalent to the reference predicate devices. The high-frequency performance of this device was substantially equally to that of predicate devices, as shown in Table 2 (Comparison chart).

Biocompatibility testing was conducted for certain materials, namely, Parylene C and PVDF used in the FH File (electrode), SUS304 used in the Grip, and SUS316 used in the Wide Contrary Electrode.

In summary, the non-clinical testing establishes that the device is substantially equivalent to the predicate devices.

807.92(b)(2): Clinical Testing

No clinical tests were performed for the Root ZX3 device.

807.92(b)(3): Conclusions from Testing

This 510(k) submission shows that the RZX3 device is substantially equivalent to the predicate devices based on its comparison with the aforementioned primary predicate, predicate, and reference devices and the data gathered during non-clinical testing.

Table 1: Comparison of RZX3 for primary predicate, apex locator

	Primary predicate
Product name	ROOT ZX II
Model	DP-ZX-VL
Manufacturer	Identical
510(k) Number	K#071190
Intended use	Identical for locating root apex function
Indications for use	Identical for locating root apex function
Target population	Identical
Patient population	Similar (broader for Root ZXII)
Anatomical sites	Identical for locating root apex function
Where used	Identical
Performance - apex locator	Identical
Standards met	Similar
Compatibility with environment and other devices	Identical
Sterility	Identical
Electrical safety	Similar
Mechanical safety	Similar
Thermal safety	Similar
Radiation safety	Similar

Table 2: Comparison of RZX3 for electrosurgical unit

	Predicate	Reference device
Product name	Bonart Art-E1 Electrosurgery Unit	X O Odontosurge 4
Model	unknown	unknown
Manufacturer	Bonart Co., Ltd.	X O Care
510(k) Number	K#020080	K#023672
Intended use	Similar in terms of electrosurgical function	Similar in terms of electrosurgical function
Indications for use	Identical in terms of electrosurgical function	Identical in terms of electrosurgical function
Target population	Similar	Similar
Patient population	Unknown	Unknown
Anatomical site	Similar	Similar
Where used	Similar	Similar
Performance - electrosurgical unit	Similar	Similar
Standards met	Similar	Similar
Materials	unknown	unknown
Compatibility with environment and other devices	Similar	Similar
Sterility	Similar	Similar
Electrical safety	Similar	Similar
Mechanical safety	Similar	Similar
Thermal safety	Similar	Similar
Radiation safety	Similar	Similar