Trident s.r.l
% Joyce St. Germain
Regulatory Consultant
The 510k Consulting LLC
1449 Springleaf Dr.
Ormond Beach, Florida 32174

September 13, 2018

Re: K182206
Trade/Device Name: RiX70 DC
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: August 8, 2018
Received: August 15, 2018

Dear Joyce St. Germain:

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,

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182206

Device Name
RiX70 DC

Indications for Use *(Describe)*
RiX70 DC X-ray Unit is designed for use in dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.

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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510(k) Summary

Submitter/Applicant

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Date Prepared: August 08, 2018

Preparer/Consultant

The 510k Consulting, LLC
Phone: 904-477-3203
Primary Contact: Joyce St. Germain, Regulatory Consultant,
joyce510kfda@gmail.com

Device Classification

Trade Name:	RiX70 DC
Common Name:	Unit, X-Ray, Extraoral with Timer
Regulation Name:	Extraoral Source X-ray System
Regulation Number:	21 CFR 872.1800
Product Code:	EHD
Regulatory Class:	II
510k Review Panel:	Dental

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K163519
Date Cleared	January 13, 2017
Trade Name:	RX DC
Common Name:	Unit, X-Ray, Extraoral with Timer
Regulation Name:	Extraoral Source X-ray System
Regulation Number:	21 CFR 872.1800
Product Code:	EHD
Regulatory Class:	II
510k Review Panel:	Dental

Indications for Use

RiX70 DC X-ray Unit is designed for use in dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.

Intended Use

The RiX70 DC is designed for the acquisition of intraoral images of the teeth, jaw and the mouth structure for diagnostic purposes.

Device Description

The subject device is **RiX70 DC X-ray Unit** and it is an extraoral source dental x-ray system intended for intraoral imaging. The subject device is a device comprised of a double mobile and articulate support arm. At the opposite ends of the arm are located, respectively:

- A control unit equipped with wall plate, extension arm and wired control device.
- A tube head with x-ray tube.

X-rays are produced using the high frequency and constant potential generators with a built in round collimator with the high frequency (HF) technology, X-ray emission at 70 kV and 7 mA (maximum power), and the x-ray unit automatically calculates the best exposure time (from 0.01 s to 2.00 s) based on the selected tooth and patient size, as well as an adjustable arm that allows for easy positioning. This device may also be adjusted manually to the user's specific radiographic technique.

The system can be used either with conventional film or a digital imaging system.

The RiX70 DC is available in two configurations: a wall-mount configuration and a floor-standing configuration, and provides for three selections of kVp: 60kVp, 65kVp, and 70kVp.

Comparison of Technological Characteristics with Predicate on next page.

The following table compares technological and other characteristics of the subject and predicate device.

Table 5.1 -- Technological Comparison

Table of Comparison

	Subject Device	Predicate Device	Comparison
Device	**RiX70 DC**	**RX DC**	**NA**
Manufacturer	Trident s.r.l., Italy	Isemed Srl, Italy	NA
510(k) Number	NA	K163519	NA
Classification & Product Code	872.1800; EHD	872.1800; EHD	Same
Device Description	Dental X-ray System	Dental X-ray System	Same
Common Name	Extraoral Source X-ray System	Extraoral Source X-ray System	Same
Indications for use	RiX70 DC X-ray Unit is designed for use in dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.	RX DC x-ray unit is designed for use in dental surgery to make endo-oral x-rays for diagnostic purposes. This equipment can be used to produce traditional x-rays developed using chemicals or, alternatively, it can be used with digital x-ray sensors.	Same
Intended use	The RiX70 DC is designed for the acquisition of intraoral images of the teeth, jaw and the mouth structure for diagnostic purposes.	Same as Indications for Use Statement	Same

Principle of use	X-ray tube	X-ray tube	Same
Installation configuration	Wall-mounted standard version and Stand mobile version	Wall-mounted standard version	Similar / Subject device has an additional option
X-ray emission control	Wired control	Remote control	**Different**
HV generator	High frequency Constant potential	High frequency Constant potential	Same
Anode material	Tungsten	Tungsten	Same
Tube voltage (kV)	60, 65, 70 kV	60 kV	**Different**
Tube current (mA)	7 mA fixed	7 mA 3.5 mA	Similar
Exposure time	0.02 sec-2 sec (R' so steps)	0.01 sec – 1 sec (in R 20 steps)	**Different**
X-ray tube & Anode angle	16˚	12.5˚	Similar
Focal spot size	0.4mm IEC 60336/1993	0.4mm	Same
Leakage radiation	< 0.25 mGy/h (@ 1 m)	< 0.25 mGy/h (@ 1 m)	Same
Focus film distance	Standard round (fix): 200 mm (8'') Standard rectangular (removable): 45x35mm	Short round (fix): 200 mm (8'') Long rectangular (removable): 300mm (12'')	**Different size**

Diameter of x-ray beam cone	Short round (fix): Ø 60 mm	Short round (fix): Ø 60 mm Long rectangular (removable): Ø 45x35mm Round (removable): Ø 55 mm	**Different size**
Exposure times control	Microprocessor controlled exposure times	Microprocessor controlled exposure times	Same
Exposure modes	Preset loading factors or manual mode	Preset loading factors or manual mode	Same
Selectable parameter	Patient type, anatomical position, film type	Patient type, anatomical position	Same
Patient type	Adult--Child	Adult--Child	Same
Tooth type	Molar (upper and lower) Premolars (upper and lower) Incisors/canines (upper and lower) Bite wing	Molar (upper and lower) Premolars (upper and lower) Incisors/canines (upper and lower) Bite wing	Same
Film type	Photo-stimulated plate or sensor	Photo-stimulated place or sensor	Same
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304 IEC 62366 ISO 14971	IEC 60601-1 IEC 60601-1-2 IEC 62304	Subject device performed more IEC standards on the device. Both passed all standards performed.

The above comparison shows the subject and predicate devices have substantially similar technology characteristics.

Non-Clinical Performance Data

The following performance data was provided in support of the substantial equivalence determination.

Non clinical tests performed on the subject device:
Safety and EMC tests conducted in compliance with the declared standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
- IEC 60601-1-6:2010
- IEC 62366: 2007
- IEC 60601-1-3:2008 (Second Edition)
- IEC 60601-2-65:2012
- IEC 60601-1-2:2007 (EMC)

For all consensus standards here above all requirements have been met. Trident has obtained a CB certificate (CBTC_IT-16415_2016-01-29) from IMQ Italy.

Software/Firmware quality activities were conducted as appropriate for a Moderate Level of Concern, and included activities for conformance with IEC 62304, *Medical device software: Software Life Cycle Processes.*

Risk Analysis Information

Risk analysis includes particular recommendations to address radiation exposure to the user under mobile operating conditions. Operators should always read the user manuals for medical devices and take the necessary precautions before using the device. Methods to reduce exposure is recommended safety precautions such as wearing personnel monitoring and protective equipment. Additional information for safety is found in the user manual for this device. Risk management was performed according to ISO 14971. This device is known as a moderate level of concern.

Conclusion

The subject and the predicate device have the same indications for use and the same intended use and the similar technological features. The RiX70 DC and the predicate, RX DC share the same principles of operation and use similar imaging firmware. The conclusion is that the subject device is as safe and effective as the predicate.

The RiX70 DC warrants a finding of substantial equivalence to the legally marketed RX DC and thus clearance for premarket activities in the United States.