August 23, 2022

FONA S.r.l
℅ Krupa Srivastava
Regulatory Consultant
Via G.Galilei 11
Assago, MILAN 20057
ITALY

Re: K222274
Trade/Device Name: FONA XDC
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: July 29, 2022
Received: July 29, 2022

Dear Krupa Srivastava:

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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)*
K222274

Device Name
FONA XDC

Indications for Use *(Describe)*
FONA XDC is an intraoral dental X-ray device intended for dental radiographic examination and diagnosis of diseases related to the anatomical structures of the teeth in both adult and pediatric patients.

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

K222274

Date Prepared:	August 10, 2022
Submitters Information	
Name	FONA s.r.l.
Address	Via G.Galilei 11 20057 Assago (MI), Italy
Contact Person	Luigi Germanò
Contact Telephone	+39 0245712171
Device Information	
Device/ Trade Name	FONA XDC
Common Name	Unit, X-Ray, Extraoral With Timer
Classification Name	Extraoral source x-ray system
Classification Regulation	21 CFR 872.1800
Product code	EHD
Classification	2

Predicate Device:
The predicate device for the FONA XDC along with its 510(k) number is provided below:

Trade Name	IntraOs 70
510(k) Number	K031118
Classification Name	Extraoral source x-ray system
Classification Regulation	21 CFR 872.1800
Product code	EHD

Classification	2

Reference Device:
The reference device for the FONA XDC along with its 510(k) number is provided below:

Trade Name	Heliodent Plus
510(k) Number	K083344
Classification Name	Extraoral source x-ray system
Classification Regulation	21 CFR 872.1800
Product code	EHD
Classification	2

Indications for use

FONA XDC is an intraoral dental X-ray device intended for dental radiographic examination and diagnosis of diseases related to the anatomical structures of the teeth in both adult and pediatric patients.

Device Description:

The device consists of an X-ray generator, a CPU that manages the exposure time and a mechanical suspension system, for wall mounting or mobile stand.

The image detectors (a necessary component for a fully-functional diagnostic system) are not part of the current submission.

The device, unlike the previous IntraOs 70 with AC power supply of the tube, is powered at constant potential, i.e. direct current, guaranteeing excellent quality of the final image. From an application point of view, FONA XDC radiographic system is similar to the IntraOs 70; it is possible to select nine anatomical zones (two more than in IntraOs 70), two patient body sizes and three types of receptors that can be set at different sensitivities.

The basic radiographic system allows to operate at 20 cm (8”) source-skin distance (SSD) with circular radiation beam. The FONA XDC primary collimator, as for the IntraOs 70, consists of a brass cylinder and the limitation

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of the beam on a circular surface of 6 cm in diameter from the focus for a working distance of 20 cm. It is possible to bring the working distance to 30 cm from the focus by adding a cone extension. It is also possible to reduce the exposed circular area both by working at 20 cm and at 30 cm, with the interposition of rectangular 3x4 cm or 2x3 cm BLD adaptor, for image receptors of size 2 (adult) or size 0 (child) respectively

Substantial Equivalence:

We believe that the FONA XDC, is substantially equivalent to the legally marketed device (the predicate device) in terms of safety and effectiveness.

The primary predicate is the FONA XDC as it is a further development to the IntraOs 70 and performs similar operations and functions.

Both the current FONA XDC and the cleared IntraOs 70 are extra oral source X-ray systems intended for dental radiographic examination and diagnosis of diseases of the teeth.

Both the IntraOs 70 and the FONA XDC are Intraoral dental X-ray devices to be used together with a proper receptor. The medical device is intended to be used in hospitals or in medical dental centers by radiology doctors, dentists and qualified staff who have received proper training. They both can be configured in the wall mounted as well as the mobile versions. The mechanical mobile stand base, the scissor arms and support arms are identical.

Although worded differently, there are no differences between the subject device and the predicate device with respect to indications and intended use.

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Comparison of the subject modified device to the cleared predicate device

	Device	Predicate Device	Reference Device
Device Name	**FONA XDC**	**IntraOs 70**	**Heliodent Plus**
Manufacturer Name	FONA S.r.l	FONA S.r.l (Formerly known as Blue X Imaging S.r.l)	Sirona Dental Systems GmbH
Product Illustration			
Device Classification Regulation	21 CFR 872.1800	21 CFR 872.1800	21 CFR 872.1800
Regulation/Classification Name	Extraoral source x-ray system	Extraoral source x-ray system	Extraoral source x-ray system
Common Name	Unit, X-Ray, Extraoral with Timer	Unit, X-Ray, Extraoral with Timer	Unit, X-Ray, Extraoral with Timer
Product Code(s)	EHD	EHD	EHD
510(k)	K222274	K031118	K083344

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	Device	Predicate Device	Reference Device
Device Name	**FONA XDC**	**IntraOs 70**	**Heliodent Plus**
Intended Use / Indications for Use	FONA XDC is an intraoral dental X-ray device intended for dental radiographic examination and diagnosis of diseases related to the anatomical structures of the teeth in both adult and pediatric patients.	The IntraOs 70 (with Autoset Timer) is intended for the dental radiographic examination and diagnosis of diseases related to the anatomical structures of the teeth. Such a device makes use of an extra oral source x-ray system commonly referred to as intraoral x-ray equipment.	The Heliodent Plus is an X-ray device for established dental surgeries and clinics intended to be used for intraoral radiography for examination and diagnosis of diseases of the teeth, jaw, and oral structures.
Power Supply	DC	AC	DC
Line Voltage	110-127 V ± 10% 220-240 V ± 10%	110-120 V (from 99 V to 132 V) 220-24 0V (from 198 V to 264 V)	120 V ± 10% 200-240 V ± 10%
Line Fuse	T 8AH at 110-127 V T 5AH at 220-240 V	6.3 A at 115 V 4 A at 230 V	16 A slow blow
Line Frequency	50-60 Hz	50/60 Hz ± 1 Hz	50/60 Hz
Line Resistance	≤ 0.5 Ohm at 110-127 V ≤ 1.0 Ohm at 220-240 V	≤ 0.4 Ohm at 115 V ≤ 0.8 Ohm at 230 V	0.3 Ohm at 120 V 0.8 Ohm at 200-240 V
Maximum Line Current	8 A at 110-127 V 5 A at 220-240 V	6 A at 120 V 4 A at 230 V	10 A at 120 V 6-5 A at 200-240 V
Focal Spot	0.4 as per IEC 60336	0.8 as per IEC 60336	0.4 as per IEC 60336
Inherent Filtration	≥ 2.3 mm Al at 70 kV	> 2.5 mm Al at 70 kVp	> 1.5 mm Al at 70
Tube Voltage	60 or 70 kV ± 5% selectable	70 kVp ± 8% at nominal line voltage 66 kVp ± 8% at nominal line voltage – 10% 74 kVp ± 8% at nominal line voltage+ 10%	60 kV / 70 kV switchable (max. tolerance ± 5 kV)
Tube Current	7 mA ± 10%	7.0 mA ± 15% at nominal line voltage 5.3 mA ± 15% at nominal line voltage – 10% 8.3 mA ± 15% at nominal line voltage + 10%	7 mA (max. tolerance ± 1.4 mA)

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	Device	Predicate Device	Reference Device
Device Name	**FONA XDC**	**IntraOs 70**	**Heliodent Plus**
Anatomical Areas	• Upper incisor • Upper cuspid / premolar • Upper molar, • Occlusal upper / lower arch • Occlusal premolar crowns • Occlusal molar crowns • Lower incisor • Lower cuspid / premolar • Lower molar	• Maxillary incisor • Maxillary canine or premolar • Maxillary molar • Mandibular incisor • Mandibular canine or premolar • Mandibular molar • Bite-wing premolar	• Maxillary front tooth • Maxillary canine / premolar • Maxillary molar • Bite-wing exposure • Mandibular front tooth • Mandibular canine / premolar • Mandibular molar
Image receptors	Film, Phosphor plate, digital sensor	Film and digital sensor	Film and digital sensor
Patient population	Adult and Child	Adult and Child	Adult and Child
Exposure time	0.01-3.2 s ± 5% R20 scale	0.06-3.2 s ± 5% R10 scale	0.01 – 3.2 s (max. tolerance ± 10% +1 ms)
Principle of Operation	The device consists of an X-ray generator, a CPU that manages the exposure time and a mechanical suspension system, for wall mounting or mobile stand. The device is powered at constant potential, i.e. direct current.	The device consists of an X-ray generator, a CPU that manages the exposure time and a mechanical suspension system, for wall mounting or mobile stand. IntraOs 70 is a traditional AC tube-head, 70 kVp, 7 mA.	The device consists of an X-ray generator, a CPU that manages the exposure time and a mechanical suspension system, for wall mounting or mobile stand. The device is powered at constant potential, i.e. direct current.
Xray exposure time control	Microprocessor controlled	Microprocessor controlled	Microprocessor controlled
Sterilization	Not Sterile, disinfect and use	Not Sterile, disinfect and use	Not Sterile, disinfect and use
Operating Conditions	Temperature 10°C to 40°C Humidity 30 to 75% Pressure 700 to 1060 hPa	Temperature 10°C to 40°C Humidity 30 to 75% Pressure 700 to 1060 hPa	Ambient temperature +10°C – +35°C With room temperatures > 35°C (> 95°F) Dentsply Sirona recommends the use of an air conditioning system. Relative humidity: 30% - 85% (no condensation)

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	Device	Predicate Device	Reference Device
Device Name	**FONA XDC**	**IntraOs 70**	**Heliodent Plus**
Performance Standards	IEC 60601-1 (Electrical Safety) IEC 60601-1-2 (EMC) IEC 60601-1-3 (Radiation Protection) IEC 60601-2-65 (Performance) IEC 60336 (Focal Spots) IEC 62304 (Software) IEC 60601-1-6 & IEC 62366-1 (Usability) IEC 61223-3-4 (performance) ISO 10993-1 (Biocompatibility) 21CFR1020.30 & 21CFR 1020.31	IEC 60601-1 (Electrical Safety) IEC 60601-1-2 (EMC) IEC 60601-1-3 (Radiation Protection) IEC 60601-2-65 (Performance) IEC 60336 (Focal Spots) IEC 62304 (Software) IEC 60601-1-6 & IEC 62366-1 (Usability) IEC 61223-3-4 (performance) ISO 10993-1 (Biocompatibility) 21CFR1020.30 & 21CFR 1020.31	IEC 60601-1 (Electrical Safety) IEC 60601-1-2 (EMC) IEC 60601-1-3 (Radiation Protection) IEC 60336 (Focal Spots) IEC 60601-2-65 (performance)

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Summary of Non Clinical Testing:

The device is an evolution of the predicate device based on experience of the predicate device from the field and in compliance with the state of the art in the dental imaging area.

FDA consensus standards have been employed for electrical safety, electromagnetic compatibility, performance and usability. Each produced device is checked against the FDA performance standards for Ionizing radiation emitting products. The performance of the predicate device and the subject device have been validated using the same testing models.

Based on the device nature (an x-ray generator similar to the predicate), clinical testing is not required to demonstrate substantial equivalence. Successful bench testing results should be enough proof that the FONA XDC works as intended.

Conclusion:

The proposed device has the same intended use and principles of operation as the predicate device.
There are no significant changes to the materials, dimensions or to the assembly process of the device. No new biocompatibility testing is deemed to be required as compared to the predicate device.

In conclusion, the FONA XDC is as safety and effective as the predicate device.

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