August 30, 2021

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

Re: K212103
Trade/Device Name: StarX-1, StarX-2, StarX PRO-1 and StarX PRO-2
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: June 30, 2021
Received: July 6, 2021

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,

, for

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K212103

Device Name
StarX-1, StarX-2, StarX PRO-1 and StarX PRO-2

Indications for Use *(Describe)*
Acquisition of intraoral X-Ray image of the human dental arch. In particular:
• The STARX-1/ STARX PRO-1 sensors (active area 20 x 30 mm) allow to acquire the majority of intraoral images both vertically and horizontally.
• The STARX-2/ STARX PRO-2 sensors (active area 26 x 34 mm) allow to acquire horizontal bitewing images.

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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K212103 **510(k) SUMMARY**

Date Prepared: June 30, 2021

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	StarX-1, StarX-2, StarX PRO-1 and StarX PRO-2
Common Name	Intraoral Digital X-Ray Sensor
Classification Name	Extraoral source x-ray system
Classification Regulation	21 CFR 872.1800
Product code	MUH

Predicate Devices:
The following legally marketed predicate device has been chosen for the determination of substantial equivalence:

Trade Name	Quick Ray HD
510(k) Number	K151926
Classification Name	Extraoral source x-ray system
Classification Regulation	21 CFR 872.1800
Product code	MUH

Indications for use

Acquisition of intraoral X-Ray image of the human dental arch. In particular:

- The STARX-1/ STARX PRO-1 sensors (active area 20 x 30 mm) allow to acquire the majority of intraoral images both vertically and horizontally.
- The STARX-2/ STARX PRO-2 sensors (active area 26 x 34 mm) allow to acquire horizontal bitewing images.

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Device Description:

The StarX-1, StarX-2, StarX PRO-1 and the StarX PRO-2 are digital intraoral sensors based on CMOS technology for intraoral X-Ray image acquisition of the human dental arch. The sensors are available in two sizes; in particular:

- StarX-1 / StarX PRO-1 sensors: active area 20 x 30 mm
- StarX-2 / StarX PRO-2 sensors: active area 26 x 34 mm

The differences between the sensors are the sizes and the different kind of scintillator (Cesium Iodide - CsI and Gadolinium Oxysulfide - GOS).

StarX-1, StarX-2, StarX PRO-1 and StarX PRO-2 are directly connected to the acquisition PC through the USB connection. Up to three sensors can be connected to one PC at time.

The type of X-ray systems that integrate with the sensors are wall-mounted X-ray intraoral generators (both AC and DC) with a tube current between 1 and 15 mA inclusive, and with a tube voltage between 50 and 100 kV inclusive, with in-built controls to set exposure parameters. Generators allow variable mA/kV to be selected, which will control the exposure time.

The sensor is supplied with an acquisition (TWAIN) module to acquire images from the sensor via the USB. The user can further process these images via a patient management software to process, filter and modify images using a software such as the Oris Win DG software which is not part of this submission.

The device cannot act as an x-ray generator controller. All control of x-ray generation is done by controls built into the generator itself. There is no connection between the subject device and the x-ray generator. The subject device does not control the generator, it is a receiver only.

Before FONA sells this device, the team discuss the hardware and software requirements of the user to make sure that their systems are compatible with the FONA sensors.

FONA provides technical support for this device to ensure proper operation and to answer any questions regarding the functioning of the device. Contact details are provided to all end users and in the user manual.

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Substantial Equivalence:

The subject device and predicate device are identical in firmware/hardware and supplied by the same company, Hamamatsu. The firmware in the FONA devices has already been cleared in the Predicate Device.

The sensor technology and principle of operation remain the same. The FONA StarX-1 and StarX-2 utilise the GOS scintillator which work on similar principles as the CSi scintillator found in the StarX PRO and the predicate devices. Clinical as well as the Non-Clinical testing performed on these FONA devices do not raise any concern of safety or effectiveness as compared to the predicate device.

The predicate device comes with Xray Vision (OTS package from Apteryx, USA) which performs image acquisition, archiving, image enhancements, electronic transmission and diagnostic review system.

The FONA sensor is supplied only with an acquisition (TWAIN) module to acquire images from the sensor via the USB. The user can further process these images via a patient management software to process, filter and modify images using a software such as the Oris Win DG software which is not part of this submission.

A comparison of the FONA sensors to the predicate device is tabulated below:

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	Subject Device	Predicate Device
Device Name	**STARX-1, STARX-2, STARX PRO-1 and STARX PRO- 2**	**Quick Ray HD**
Manufacturer Name	FONA S.r.l	Denterprise International
Device Classification Regulation	21 CFR 872.1800	21 CFR 872.1800
Common Name	Intraoral Digital X-Ray Sensor	Intraoral Digital X-Ray Sensor
Classification Name	Extraoral Source X-Ray System	Extraoral Source X-Ray System
Product Code(s)	MUH	MUH
Regulatory Class	2	2
510(k)	Not yet assigned	K151926
Intended Use	The acquisition of intraoral X-Ray image of the human dental arch. In particular: • The size 1 sensor allows to acquire the majority of intraoral images both vertically and horizontally. • The size 2 sensor allows to acquire horizontal bitewing images.	Radiographic examination to assist with diagnosis of diseases of the teeth, jaw, and oral structure. The QuickRay HD dental sensor is intended to replace film and to capture an intraoral x-ray image, when exposed to X-rays, for dental diagnostic purposes.
Software	TWAIN (Standard) Module which is a communication protocol used for image acquisition only. It works with any compatible patient management system.	Xray Vision (OTS package from Apteryx, USA) K983111- performs image acquisition, archiving, image enhancements, electronic transmission and diagnostic review system.
Principles of Operation	X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital) => electronics => PC (capture & display image)	X-ray (radiation) => scintillator (convert to light) => fiber optic (filtering) => CMOS (convert to digital) => electronics => PC (capture & display image)

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	Subject Device	Predicate Device
Device Name	**STARX-1, STARX-2, STARX PRO-1 and STARX PRO- 2**	**Quick Ray HD**
Software-Firmware	Firmware combined on sensor electronic board	Firmware combined on sensor electronic board
Sensor technology	**STARX PRO:** CMOS + Optical fiber plate + CSi **STARX:** CMOS+ Optical Fiber plate + GOS	CMOS chip + optical fiber plate + CSi
Matrix dimensions (mm^2)	(Size 1) STARX-1 and STARX PRO-1: 600mm^2 (Size 2) STARX-2 and Starx PRO-2: 884mm^2	Active area: 600mm^2 (Size 1) 884mm^2 (Size 2)
Matrix dimensions (pixels)	1000 x 1500 (STARX-1 and STARX PRO-1) 1300 x 1700 (STARX-2 and STARX PRO-2)	1000 lines X 1500 columns (Size 1) 1300 X 1700 (Size 2).
Resolution	**STARX-** 12lp/mm **STARX PRO-** 20lp/mm	Real ≥ 20lp/mm
Pixel Size	20x20 µm	20x20 µm
Sterilization	Not sterile. Disinfect and use	Not sterile. Disinfect and use
Shelf life/ Lifespan CMOS	Min. 125,000 cycles	Min. 100,000 cycles
Grey Levels	14 bits	14 bits
Sensor Board	All control electronics directly integrated on CMOS sensor chip	All control electronics directly integrated on CMOS sensor chip
Sensor shell	Enclosure for sensor is ABS and the flammability is HB of UL-94 (UL File No.49895)	Specific shape design; material is ABS and the flammability is HB if YK- 94 (UL File No. 49895)
Cable material and design	Cable consists of PVC, ETFE, Copper, plug connector and sensor connector, diameter ø3.7 ±0.3 and cable length of 2 meters	Cable consists of PVC, ETFE, copper, plug connector and sensor connector, diameter ø3.7 ±0.3 and cable length 2 meters.
Connection to imaging practice PC	USB 2.0 High-Speed	USB 2.0 High-Speed

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	Subject Device	Predicate Device
Device Name	**STARX-1, STARX-2, STARX PRO-1 and STARX PRO- 2**	**Quick Ray HD**
Operating temperature	0°C to 35°C	0°C to 35°C
Sensor input voltage and current	5V (via USB connection); 0.15A Max	5V (via USB connection); 0.15A Max
Performance Standards	IEC 60601-1 (Electrical) IEC 60601-1-2 (EMC) IEC 60601-1-6 & IEC 62366-1 (Usability) IEC 61223-3-4 (performance) IEC 62220-1 (DQE-performance) IEC 60529 (IP Code)	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC) 62220-1 (Performance) 60529 (IP Code)

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The comparison table reveals there are no new technical issues of safety or effectiveness raised by the substitution of the scintillator. Professional evaluation of imaging samples were found to be of good quality, high resolution, clinically acceptable and substantially equivalent to the predicate device.

Summary of Non Clinical Testing: IEC standards have been employed for Electrical Safety, Electromagnetic Compatibility, performance and usability. The panel power supply is UL Listed. The CMOS area image sensor manufacturer conducted performance testing according to the FDA guidance document for solid state digital X-ray panels. Risk Analysis and System operation verification tests were conducted in accordance with FDA guidance documents. Labelling was developed to comply with the FDA solid state panel guidance document.

Summary of Clinical Testing: Sample clinical images from the FONA device were evaluated as per the FDA guidance document for solid state digital X-ray panels and found to be clinically adequate.

Conclusion: After analysing non-clinical data, electrical safety as well as clinical evaluation, it can be concluded that the FONA devices are as safe and effective as the predicate device, has few technological differences, and has no new intended use, thus rendering it substantially equivalent to the predicate device.

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