DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 3, 2016

FONA Srl
% Ms. Elisa Gusberti
Quality and Regulatory Affairs Manager
Via Galileo Galilei 11
Assago, Milan 20090
ITALY

Re: K161131
Trade/Device Name: FONA Pan/Ceph
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: September 14, 2016
Received: September 16, 2016

Dear Ms. Gusberti:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161131

Device Name

FONA Pan/Ceph

Indications for Use *(Describe)*

The FONA Pan/Ceph device, comprising models FONA XPan DG, FONA XPan DG Plus, FONA ART Plus, and FONA ART Plus C, is an extraoral source dental X-ray system intended to perform panoramic or cephalometric exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry, as well as carpal 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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1 510(k) Summary

1.1 Company and correspondent making the submission

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Date prepared:	April 15, 2016

1.2 Device

Device trade name:	FONA Pan/Ceph
Device models:	FONA XPan DG, FONA XPan DG Plus, FONA ART Plus, FONA ART Plus C
Regulation number:	21CFR 872.1800
Regulation name:	Extraoral source x-ray system
Classification:	II
Product code:	MUH

1.3 Predicate devices

The new FONA Pan/Ceph device is substantially equivalent to the following legally marketed predicate devices:

- PantOs (K031801) manufactured by Blue X Imaging Srl, the former company name of FONA Srl, primary predicate device:
  - Regulation name: Extraoral source X-ray system
  - Product codes: MUH, EHD, MQB.
- ORTHOPHOS SL (K150217) manufactured by Sirona Dental Systems GmbH, which incorporates, for the panoramic and cephalometric modalities, the same types of image receptors used in the new FONA Pan/Ceph device:
  - Regulation name: Computed Tomography X-ray system
  - Product code: OAS.

1.4 Indications for use

The FONA Pan/Ceph device, comprising models FONA XPan DG, FONA XPan DG Plus, FONA ART Plus, and FONA ART Plus C, is an extraoral source dental X-ray system intended to perform panoramic or cephalometric exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry, as well as carpal images.

1.5 Device description

The FONA Pan/Ceph device is an X-ray equipment designed for:

- Dental panoramic radiography
- Cephalometry, when completed with lateral Ceph arm.

The FONA Pan/Ceph device comprises four models:

- FONA XPan DG and FONA XPan DG Plus, with CCD type of image receptor with CsI scintillator
- FONA ART Plus, FONA ART Plus C, with CMOS type of image receptor with Cd(Zn)Te scintillator.

All the models allow for panoramic projections and two of them are extended with cephalometric functionality:

- The models FONA XPan DG and FONA ART Plus feature panoramic projections only (type Pan Solo) and are thus equipped with a fixed image receptor mounted on the rotating arm.

- The models FONA XPan DG Plus and FONA ART Plus C feature panoramic and cephalometric projections (type Pan Ceph) and are equipped with a detachable image receptor to be placed on the rotating arm, for the panoramic modality, or on the cephalometric arm, for the cephalometric modality.

The control panel on the unit contains keys and signaling lights for a complete control of the operation and for the setting of the desired technique factors.

Class I LASER aiming lights support positioning of patient's head, which is stabilized through the use of bite blocks, chin rest, and, in case, temple supports.

The user controls the exposure using a manual hand-switch, implementing the dead man functionality.

An Ethernet connection cable allows the FONA Pan/Ceph device to interface with a computer for image acquisition, processing and storage.

The user may thus view and store the radiographic images using a software installed on a side computer with peripheral components such as a mouse, keyboard, and monitor. The software takes care of acquisition, processing, displaying, and archiving the image data.

A TWAIN interface is also available for interfacing to other existing programs with processing and storage capabilities, according to the user's needs.

1.5.1 Scientific concept

The panoramic and cephalometric radiographs are based on traditional technologies which have been used for a long time.

1.5.2 Physical and performance characteristics

The FONA Pan/Ceph device has a vertical carriage with a rotating arm plus a lateral arm for the cephalometric models, to which the power supply cord, the Ethernet cable and the exposure hand-switch are connected.

The equipment can be raised or lowered during patient positioning with the motorized movement along a column.

The rotating arm is equipped with the tube housing assembly, the housing for the image receptor and the control panel.

The arm carrying the Cephalostat and the housing for the digital sensor is fixed to the vertical carriage.

The panoramic radiographic image of the dental arch is made with a thin vertical X-ray beam out of the rotating arm which turns around and scans the head of the patient.

The cephalometric radiographic image, on the applicable models, is produced with a thin vertical X-ray beam that horizontally scans the head of the patient.

The FONA Pan/Ceph device features an anode voltage from 61 to 85 kV (at constant potential), with anode current from 4 to 10 mA (direct current, DC).

In panoramic modality the source to image receptor distance is of 51.3 cm (20.2"), and the exposure time ranges from 4.4 s up to 14.2 s, depending on the selected panoramic program.

In cephalometric modality, for the applicable models, the source to image receptor distance is of 165 cm (65"), and he exposure time is of 8 or of 10 s, depending on the cephalometric program.

Specific accessories like bite block, chin rest, nasal support, are provided to permit correct patient positioning. A head rest made of two temporal resting bars is optionally provided.

The cephalometric models come with cephalostat with nasion reference and side bars with ear plugs to stabilize the head during exposure plus a hand-rest panel for the radiograph of the hand.

These patient positioning items are likely to enter in contact with the patient during the normal use of the FONA Pan/Ceph device. The use of standard hygienic protective sleeves (not included in the scope of supply) to avoid cross-contamination among patients, operators and other persons, is recommended.

The FONA Pan/Ceph device with its associated accessories fulfils the biocompatibility requirements of ISO 10993-1:2010.

1.6 Summary of technological characteristics

The new FONA Pan/Ceph device is directly derived from the PantOs (K031801), model PantOs DG xp, making use of:

- Same X-ray generator and tube housing assembly
- Same electronic boards for power control
- Same mechanical structure (carriage and column) and type of stepping motors for carriage movements
- Same core of embedded software (FW) for control of mechanical movements, X-ray generation, service functionalities
- Same LASER sources for aiming lights to support patient positioning.

The new FONA Pan/Ceph device incorporates changes to the PantOs device, model PantOs DG xp, comprising:

- Addition of a Ceph arm with scanning system driven by the same control unit
- Addition of a motorized collimator driven by the same control unit
- Addition of motorization of the vertical travel of the carriage on the column for an easier patient positioning
- Adoption of up-to-grade image receptors based on CsI or Cd(Zn)Te high yield scintillators instead of the traditional Gd2O2S:Tb (Gadolinium oxide, Terbium doped, of LANEX™ screens by Kodak) less efficient (thus giving a less favorable signal to noise ratio).

The new FONA Pan/Ceph device incorporates the same basic features of the predicate device ORTHOPHOS SL (K150217), models ORTHOPHOS SL 2D and ORTHOPHOS SL 2D Ceph:

- Panoramic radiology with selected projections
- Cephalometric radiology with scanning modality
- Use of CCD image receptor with CsI scintillator
- Use of CMOS image receptor with Cd(Zn)Te scintillator
- Use of motorized collimator
- Use of motorization of the vertical travel of the carriage.

1.7 Non-clinical performance testing

The new device FONA Pan/Ceph has been tested for Electrical Safety and Electromagnetic Compatibility and complies with the standards:

- IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

A qualitative assessment of the image quality of the new FONA Pan/Ceph device has been carried out in comparison to the predicate devices. As a result, it has been confirmed that the image receptors used in the new FONA Pan/Ceph device and in the predicate devices, all allow for good diagnosis, both in panoramic and cephalometric images. However, the new types of image receptors, based on CsI or Cd(Zn)Te scintillators, adopted in the new FONA Pan/Ceph device, provide clearer pictures due to a better signal to noise ratio, compared to those based on traditional Gd_2O_2S:Tb (Gadolinium of LANEX™ screens by Kodak) scintillators.

Additional tests have been performed taking into account FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, Document issued on: August 6, 1999". In particular, DQE and MTF data have been provided for the CCD image receptors based on CsI(Tl) scintillator, optically coupled, and for the direct conversion CMOS ones with Cd(Zn)Te absorber material, to demonstrate substantial equivalence.

These additional tests have been integrated with bench testing performed with an anthropomorphic phantom for the panoramic and cephalometric modes on the new device and on the predicate ones.

Software verification and validation testing of the new device has been performed according to the FDA Guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

1.8 Conclusion

Based on the comparison of intended use, technological characteristics and performance specifications, FONA Srl believes that the new FONA Pan/Ceph device is safe and effective and substantially equivalent to the predicate devices.