March 2, 2022

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

Re: K213579
Trade/Device Name: Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: January 25, 2022
Received: January 14, 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
Assistant Director
Diagnostic X-ray Systems Team
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)*
K213579

Device Name
Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph

Indications for Use *(Describe)*

Stellaris 2D: Extraoral source dental X-ray system intended to perform panoramic exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry.

Stellaris 2D Ceph: Extraoral source dental X-ray system intended to perform panoramic and 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 for dental clinical investigations.

Stellaris 3D: Extraoral source dental X-ray system intended to perform 3D and panoramic exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry.

Stellaris 3D Ceph: Extraoral source dental X-ray system intended to perform 3D, panoramic and 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 for dental clinical investigations.

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 K213975

Date Prepared:	January 11, 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	Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph
Common Name	X-Ray, Tomography, Computed, Dental
Classification Name	Computed Tomography X-ray system
Classification Regulation	21 CFR 892.1750 - Computed Tomography X-ray system
Product code	OAS

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

Primary Predicate Device

Trade Name	ORTHOPHOS SL
510(k) Number	K150217
Classification Name	Computed Tomography X-ray system
Classification Regulation	21 CFR 892.1750
Product code	OAS

Reference Device

Trade Name	FONA XPan DG, XPan DG Plus, ART Plus & ART Plus C
510(k) Number	K161131
Classification Name	Extraoral Source X-Ray System
Classification Regulation	21 CFR 872.1800
Product code	MUH

Indications for use

Stellaris 2D: Extraoral source dental X-ray system intended to perform panoramic exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry.

Stellaris 2D Ceph: Extraoral source dental X-ray system intended to perform panoramic and 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 for dental clinical investigations.

Stellaris 3D: Extraoral source dental X-ray system intended to perform 3D and panoramic exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry.

Stellaris 3D Ceph: Extraoral source dental X-ray system intended to perform 3D, panoramic and 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 for dental clinical investigations.

Device Description:

Stellaris 3D is a dental X-ray system for Panoramic and Cone Beam Computed Tomography (CBCT) which allows to perform all the radiographic projections, both 2D and 3D, of most interest for the dentist, the surgeon and the maxilla-facial radiologist.

In addition to the functions of Panoramic and 3D radiography, Stellaris 3D Ceph also allows to perform One-Shot Cephalometric radiographs.

Stellaris 2D is a dental X-ray system for Panoramic which allows to perform all the radiographic projections of most interest for the dentist, the surgeon and the maxilla-facial radiologist.

In addition to the functions of Panoramic, Stellaris 2D Ceph also allows to perform One-Shot Cephalometric radiographs.

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Except for the panoramic acquisition sensor, the remaining mechanical, electrical and software characteristics of Stellaris 2D are exactly identical to those of Stellaris 3D.

The control panel interface on the unit provides 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, if required, temple supports.

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

An Ethernet connection cable allows the FONA Stellaris devices to interface with a computer for image acquisition, processing and storage.

The following table describes the functionality of each model.

	Stellaris 3D	**Stellaris 3D Ceph**	**Stellaris 2D**	**Stellaris 2D Ceph**
X-ray Programs	Pan: 9 programs 3D: 23 programs Ceph: N/A	Pan: 9 programs 3D: 23 programs Ceph: 4 programs	Pan: 9 programs 3D: N/A Ceph: N/A	Pan: 9 programs 3D: N/A Ceph:4 programs
Exposure Times	Pan: max 14.2 s 3D: max 16.9 s Ceph: N/A	Pan: max 14.2 s 3D: max 16.9 s Ceph: max 4 s	Pan: max 14.2 s 3D: N/A Ceph: N/A	Pan: max 14.2 s 3D: N/A Ceph: max 4 s
Sensor Technology	Pan/3D: CMOS sensor 15x15 cm Ceph: N/A	Pan/3D: CMOS sensor 15x15 cm Ceph: CsI flat panel 24.4x30.7 cm	Pan: CMOS sensor 15x0.6 cm Ceph: N/A	Pan: CMOS sensor 15x0.6 cm Ceph: CsI flat panel 24.4x30.7 cm
Sensor Characteristics	Pan: pixel size 100 µm 3D: voxel size down to 79 µm Ceph: N/A	Pan: pixel size 100 µm 3D: voxel size down to 79 µm Ceph: pixel size 120 micron	Pan: pixel size 100 µm 3D: N/A Ceph: N/A	Pan: pixel size 100 µm 3D: N/A Ceph: pixel size 120 micron
IEC Classification	Class I, Type B			
Nominal line	230 V ± 10%, 115 V ± 10%,			

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	Stellaris 3D	Stellaris 3D Ceph	Stellaris 2D	Stellaris 2D Ceph
voltage				
Nominal line frequency	50/60 Hz			
Nominal current absorption	MAX 10 A @ 230 V, MAX16 A @ 115 V			
Line fuse	T8 A 250V for 230 V version; T15 A 250V for 115 V version			
Mains Resistance	≤ 0.8 Ohm at 230 V, ≤ 0.4 Ohm at 115 V			
Rating	1450W			
Curve form of high voltage	High frequency multi-pulse, ripple ≤ 4%			
X-ray Tube	OPX/105			
Tube voltage	60 - 86 kV ± 5%, constant potential			
Tube current	2.5 - 10 mA ± 10%, direct current (DC)			
Focal spot	0.5 IEC 60336			
Total filtration	> 2.5 mm Al /70 kV IEC 60522			
Maximum duty cycle	1/8			
Anatomical selection	4 Patient size levels: Small, Medium, Large, Extra Large			
kV setting	14 positions in 2 kV steps: from 60 to 86kV			
mA setting	7 positions according to R'10 scale: 2.5, 3.2, 4, 5, 6.3, 8, 10 mA			
Aiming lights	3 laser planes: Median Sagittal Vertical, Canine and Frankfurt Horizontal			
Laser beam Class	I			
Laser wavelength	650 nm			
Laser Output Power	< 0.15 mW at 100 mm			

FONA provides technical and maintenance 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.

Substantial Equivalence:

The FONA Stellaris 3D has a rotating arm which performs motor-driven rototranslatory movements that drive the tube housing assembly and the image detector around the patient head according to different orbits that follow the morphologic profile of the patient.

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The tube housing assembly includes an X-ray generator that generates a beam of X-ray as per the inputs selected by the user. Depending on the imaging selection i.e. 2D/panoramic, cephalometric or 3D volume reconstructions, the sensors transform the X-rays into electrical signals.

The Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D, Stellaris 3D Ceph devices contain the same type of X-ray tube as the FONA XPan DG, FONA XPan DG Plus, FONA ART Plus and FONA ART Plus C devices. The X-ray generator in the ORTHOPHOS SL device is similar in technology as compared to the FONA Stellaris devices.

The construction of the panoramic image of the dental arch is made with a thin X-ray vertical beam from the left to the right of the patient. 3D volume reconstruction is obtained from the acquisition of two-dimensional radiographic images (15x15 cm) via the cone-beam technology, then elaborated with a reconstruction algorithm.

Stellaris 2D is equipped with a CMOS sensor that allows the acquisition of panoramic images. The reconstruction is obtained from the acquisition of two-dimensional radiographic images (15x 0.6 cm) then elaborated with a reconstruction algorithm.

Stellaris 2D Ceph and Stellaris 3D Ceph, in addition, is equipped with a cephalometric arm mountable on Stellaris 2D/ Stellaris 3D respectively, which includes a one shot X-Ray sensor and a cephalostat to hold the patient in position during the examination.

Accessories like bite block, chin rest, nasal support, temporal resting bars are provided to permit correct patient positioning.

The cephalometric models come with nasion reference and side bars with ear plugs to stabilize the head during exposure.

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

The Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D, Stellaris 3D Ceph devices with its associated accessories fulfil the biocompatibility requirements of ISO 10993-1:2018.

The panoramic and cephalometric exposures are obtained by standard technology that have been used in dental medicine for a very long time. The principle of operation of the Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D, Stellaris 3D Ceph devices remains the same as the predicates. The difference is the type of sensors used which work on similar principles as the sensors found in the predicate devices.

The ORTHOPHOS SL predicate device utilises the SIDEXIS software tool for image acquisition, administration, analysis & diagnosis and the images can be stored in the SIDEXIS database.

The Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D, Stellaris 3D Ceph devices can be used with the OrisWin DG Suite software for image acquisition and database (not part of this submission), same as the FONA XPan DG, FONA XPan DG Plus, FONA ART Plus and FONA ART Plus C devices.
The use of this software is not mandatory. Any software that allows the viewing and management of radiographic images in DICOM format can also be used.

Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D, Stellaris 3D Ceph devices have more volume sizes, positions and collimations than the predicate devices. This results in more possibilities to get an exposure of relevant dento maxillofacial areas.

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	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
Manufacturer Name	FONA S.r.l	Sirona Dental Systems GmbH	FONA S.r.l
Device Classification Regulation	21 CFR 892.1750	21 CFR 892.1750	21 CFR 872.1800
Classification Name	Computed Tomography X-ray system	Computed tomography x-ray system	Extraoral Source X-Ray System
Product Code(s)	OAS	OAS	MUH
Regulatory Class	2	2	2
510(k)	K213579	K150217	K161131
Indications for Use	**Stellaris 2D:** Extraoral source dental X-ray system intended to perform panoramic exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry. **Stellaris 2D Ceph:** Extraoral source dental X-ray system intended to perform panoramic and 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 for dental clinical investigations.	The X-ray system creates data for digital exposures in the maxillofacial area and in subareas for dentistry, including pediatric dentistry, for hard-tissue diagnostics within ENT medicine, and for carpus exposures.	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.

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	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
	Stellaris 3D: Extraoral source dental X-ray system intended to perform 3D and panoramic exams with production of diagnostic images in the dento-maxillo-facial region and in subregions, for general and pediatric dentistry. **Stellaris 3D Ceph:** Extraoral source dental X-ray system intended to perform 3D, panoramic and 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 for dental clinical investigations.		
Panoramic Programs	P1: Adult Full P2: Child Full P3: Adult Partial Front P4: Adult Partial Left P5: Adult Partial Right P6: Adult Dentition P7: Sinuses P8: Bitewing P9: TMJ Open/Closed Mouth	P1: Panoramic exposure P1A: Panoramic exposure, artifact-reduced P1C: Panoramic exposure, constant 1.25x magnification P2: Panoramic exposure, without ascending rami P2A: Artifact-reduced panoramic exposure without ascending rami	P1 Standard Panoramic Adult P2 Panoramic Child P3 Left Dentition P4 Right Dentition P5 Anterior Dentition P6 TMJ lateral view open/closed mouth P7 Frontal View of Maxillary Sinuses P8 Bitewing (only FONA Art Plus / FONA ART Plus C)

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	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
		P2C: Panoramic exposure without ascending rami at a constant magnification of 1.25x P10: Panoramic exposure for children P10A: Panoramic exposure for children, without ascending rami, artifact-reduced P10C: Panoramic exposure for children, without ascending rami, constant 1.25x magnification P12: Thick slice, anterior tooth region BW1: Bitewing exposures in the posterior tooth region BW2: Bitewing exposures in the anterior tooth region TM1.1/TM1.2: Temporomandibular joints from a lateral aspect with the mouth open and closed, two-part exposure TM3: Temporomandibular joints lateral, ascending rami S1: Paranasal sinuses S3: Paranasal sinuses, linear slice orientation	
Cephalometric Programs	C1: LL (Latero-Lateral) large view C2: LL (Latero-Lateral) small view C3: AP (Anterior-Posterior) / PA (Postero-Anterior) view C4: CEPH Carpus	C1: Posterior-anterior exposure, symmetrical C2: Anterior-posterior exposure, symmetrical C3: Lateral exposure C3F: Full-format exposure, lateral	FONA XPan DG Plus: • P8 Antero-posterior • P9 Letro-lateral • P10 Carpus FONA ART Plus C • P9 Antero-posterior

	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
		C4: Carpus view, symmetrical	• P10 Latero-lateral • P11 Carpus
3D Reconstructions (for 3D model only)	V1: Adult Full View V2: Adult Upper Jaw – Surgical/ Implant V3: Adult Lower Jaw – Surgical/ Implant V4: Adult Sinuses V5: Child Full V6: Child Upper Jaw - Surgical/ Implant V7: Child Lower Jaw - Surgical/ Implant V8: Child Sinuses V9: Upper+Lower Jaws - Surgical/Implant Front V10: Upper+Lower Jaws - Surgical/Implant Left V11: Upper+Lower Jaws - Surgical/Implant Right V12: Upper Hemi-Arc Left (1 quadrant) V13: Upper Hemi-Arc Right (1 quadrant) V14: Lower Hemi-Arc Left (1 quadrant) V15: Lower Hemi-Arc Right (1 quadrant)	VOL1 (HS, SD, Low): Volume exposure with a diameter of approx. 8 cm and a height of approx. 8 cm or 5.5 cm collimated. VOL2 (HS, SD, Low): Volume exposure with a diameter of about 5 cm and a height of about 5.5 cm for upper or lower mandible. VOL3 (HS, SD, Low) (optional): Volume exposure with a diameter of about 11 cm and a height of about 10 cm or selection of upper quadrant collimated to 7.5 cm and selection lower quadrant collimated to8.0 cm	Not Available

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	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
	V16: Upper Jaw Endo Front V17: Upper Jaw Endo Left V18: Upper Jaw Endo Rright V19: Lower Jaw Endo Front V20: Lower Jaw Endo Left V21: Lower Jaw Endo Right V22: TMJ Left V23: TMJ Right		
DAP Pan Dose Area Product (approx. values)	Complete range (Ceph, 3D and 2D): 7 - 4411 mGy*cm^2.	Complete range (Ceph, 3D and 2D): 1.2 – 3056 mGy*cm^2.	Complete range : 3-247 mGy cm2
Image Acquisition Technology	Pan/2D: CMOS sensor 15 x 0.6 cm Pan/3D: CMOS sensor 15 x 15 cm Ceph: CsI flat panel 24.4 x 30.7 cm	Pan: CMOS sensor 14.6 x 0.6 cm 3D: Flat Panel sensor 16 x 16 cm Ceph: CCD sensor 23 x 0.648 cm	FONA ART Plus/FONA ART Plus C - Multi-element Cd(Zn)Te-CMOS sensor Pan-15.1 x 0.64cm Ceph- 22.66 x 0.64 cm FONA XPan DG/ FONA XPan DG Plus- Digital TDI CCD line sensor Pan- 15.06x 0.69cm Ceph- 22.1 x 0.69cm
Sensor characteristics	Pan: 100 µm Ceph: 120 µm 3D: voxel size down to 79 µm	Pan: 0.1 mm Ceph: 0.027 mm 3D: voxel size 80 - 220 µm	FONA ART Plus/ FONA ART Plus C: 100 µm FONA XPan DG/ FONA XPan DG Plus: 108 µm 3D: N/A
Spatial Resolution	Pan Sensor: 5 lp/mm 3D/Pan Sensor: 5 lp/mm	Pan sensor: 5 lp/mm 3D/Pan sensor: 4 lp/mm	FONA Xpan DG/ FONA XPAN DG plus sensor: 7 lp/mm

	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
	Ceph Sensor: 3.1 lp/mm	Ceph sensor: 2.5 lp/mm	FONA ART Plus/ FONA ART Plus C sensor: 5 lp/mm
A/D Conversion	Pan sensor: 14 bits 3D/Pan sensor: 14 bits Ceph sensor: 16 bits	Pan sensor: 12 bits 3D/Pan sensor: 16 bits Ceph sensor: 12 bits	FONA Xpan DG/ FONA XPAN DG plus: 16 bits FONA ART Plus/ FONA ART Plus C: 12 bits
Nominal voltage	230 V ± 10%, 115 V ± 10%	200 – 240 V ± 10%	230 V ± 10%, 115 V ± 10%
Mains Resistance	≤ 0.8 ohm at 230 V, ≤ 0.4 ohm at 115 V	max. 0.8 ohms	≤ 0.8 ohm at 230 V, ≤ 0.4 ohm at 115 V
Nominal frequency	50 / 60 Hz	50 / 60 Hz	50 / 60 Hz
Tube Voltage	60 - 86 kV ± 5%	60 – 90 kV	61 - 85 kV± 5%
Tube current	2.5 - 10 mA ± 10%, DC	3 – 16 mA	4 - 10 mA± 10%, DC
Exposure times	Pan: max 14.2 s Ceph: max 4 s 3D: max 16.9 s	Pan: max 14.4 s Ceph: max 14.9 s 3D: max 14.9 s	Pan: 14.2 s Ceph: 10 s 3D: N/A
Curve form of high voltage	High frequency multi-pulse, ripple ≤ 4%	High-frequency multipulse Residual ripple ≤ 4 kV	High frequency multi-pulse, ripple ≤ 4%
Focal Spot	0.5 as per IEC 60336	0.5 as per IEC 60336	0.5 as per IEC 60336
X-ray insert	OPX/105	Siemens SR 90/15 FN	OPX/105
Principles of Operation	Stellaris 3D has a rotating arm mounted on a column support. The rotating arm performs motor-driven roto-translatory movements that allow moving the X-ray emission system and the image detector around the patient according to different orbits that	The device comprises image receptors for cephalometric exposures, 2D panoramic radiographs and 3D volume exposures. The combination of sensors in the device varies depending on the installed options and the regions of interest can be altered.	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

	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
	follow the morphologic profile of the patient. Stellaris 3D Ceph, in addition, is equipped with a tele-X-ray arm coupled to the column support. The arm hosts a one-shot X-Ray sensor for the detection of X-Ray image and a cephalostat to hold the patient in position during the examination. Stellaris 2D and Stellaris 2D Ceph derive directly from the Stellaris 3D and Stellaris 3D Ceph devices, in which only the 3D sensor has been replaced with a 2D sensor.		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.
Sterilization	Not sterile. Disinfect and use	Not sterile. Disinfect and use	Not sterile. Disinfect and use
Connection to imaging practice PC	Ethernet cable	Ethernet cable	Ethernet cable
Operating Conditions	Temperature:10 to 40 °C Humidity: 30 to 75% Pressure: 700 to 1060 hPa	Temperature:18 to 31 °C Humidity: 30 to 85% Pressure: 700 to 1060 hPa	Temperature:10 to 40 °C Humidity: 30 to 75% Pressure: 700 to 1060 hPa
Performance Standards	IEC 60601-1 (Electrical Safety) IEC 60601-1-2 (EMC) IEC 60601-1-3 (Radiation Protection) EN 60601-2-63 (Performance) EN 60336 (Focal Spots) EN 62304 (Software)	EN 60601-1 (Electrical Safety) IEC 60601-1-2 (EMC) IEC/EN 60601-1-3 (Radiation Protection) IEC 60601-2-63 (Performance) IEC 60601-1-6 & IEC 62366 (Usability) IEC 60336 (Focal Spots)	IEC 60601-1 (Electrical); IEC 60601-1-2 (EMC) IEC 60601-1-3 (Radiation Protection) EN 60601-2-63 (performance) IEC 60336 (Focal spots) EN 62304 (Software) IEC 60601-1-6 & IEC 62366-1

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	Subject Device	Predicate Device	Reference Device
Device Name	**Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D and Stellaris 3D Ceph**	**ORTHOPHOS SL 2D, ORTHOPHOS SL 2D Ceph, ORTHOPHOS SL 3D and ORTHOPHOS SL 3D Ceph**	**FONA XPan DG, FONA XPan DG Plus, FONA ART Plus & FONA ART Plus C**
	IEC 60601-1-6 & IEC 62366-1 (Usability) EN 60825-1 (Laser Safety) ISO 10993-1 (Biocompatibility)	EN 62304 (Software) IEC 60825-1(Laser Safety) IEC 62471 (Lamps Photobiological safety) ISO 10993-1(Biocompatibility)	(Usability) EN 60825-1 (Laser Safety) ISO 10993-1 (Biocompatibility)

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Summary of Non Clinical Testing:

IEC standards have been employed for Electrical Safety, Electromagnetic Compatibility, performance and usability. Additionally, the CMOS area image sensor manufacturer has 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 and performance as well as clinical evaluation, it can be concluded that the Stellaris 2D, Stellaris 2D Ceph, Stellaris 3D, Stellaris 3D Ceph 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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