July 10, 2023

Trident s.r.l
% Mrs. Joyce St. Germain
Regulatory Consultant, owner
The 510k Consulting, LLC
1449 Springleaf Drive
ORMOND BEACH FL 32174

Re: K222666
Trade/Device Name: X-VIEW 3D PAN/X-VIEW 2D PAN
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: November 1, 2022
Received: November 2, 2022

Dear Mrs. 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/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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K222666

Device Name
X-VIEW 3D PAN/X-VIEW 2D PAN

Indications for Use *(Describe)*
The X-View 3D PAN/X-View 2D PAN panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images of examined volume for the reconstruction of 3D view. The X-View 3D PAN/X-View 2D PAN dental panoramic and cephalometric device is intended for general populations as long as they are older than 10 years.

The device must only be operated and used by dentists and other legally qualified professionals.

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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The 510k Consulting,LLC

Key to success in obtaining your medical device clearance

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510(k) Summary K222666

I. Submitter

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Primary Contact: Joyce St. Germain, Regulatory Consultant, joyce510kfda@gmail.com

Date Prepared: September 2, 2022

II. Device

Trade Name:	X-VIEW 3D PAN / X-VIEW 2D PAN
Common Name:	Dental X-ray System
Regulation Name:	Computed Tomography X-Ray System
Regulation Number:	21 CFR 892.1750
Medical Specialty:	Radiology
Regulation Class:	II
Product Code:	OAS
Submission Type:	510(k)

III. Predicate Device

510(k) Number:	K160166
Date Cleared:	November 15, 2016
Manufacturer:	de Gotzen S.r.l.
Trade Name:	X-MIND trium

Common Name: Dental X-ray System
Regulation Name: Computed Tomography X-Ray System
Regulation Number: 21 CFR 892.1750
Medical Specialty: Radiology
Regulatory Class: II
Product Code: OAS, MUH

Secondary Predicate

510(k) Number: K182198
Date Cleared: January 31, 2019
Manufacturer: Yoshida Dental Mfg. Co., Ltd.
Trade Name: Panoura X-ERA PF/NF/MF
Common Name: Dental X-ray System
Regulation Name: Extraoral source x-ray system
Regulation Number: 21 CFR 872.1800
Medical Specialty: Radiology
Regulatory Class: II
Product Code: MUH

This predicate has not been subject to a design-related recall.

IV. Device Description

The X-View PAN is manufactured by Trident s.r.l. and it can be sold under two different commercial names:

- X-View 3D PAN
- X-View 2D PAN

Both devices, depending on the configuration chosen, can be equipped with a cephalometric arm equipped with a 24x30 cm flat panel sensor for the execution of cephalometric radiographs of various formats and latero-lateral and antero-posterior projections. The cephalometric device can also be added in the field.

The device can be set in the configurations: Floor version with column and wall bracket and Floor version with column and standard base.

The subject dental X-ray system X-View is supported by software (firmware). The software is of Moderate Level of concern and is FDA-cleared.

Sensor details for X-View 3D PAN

Characteristics	Value
Manufacturer	iRay Technology
Model	Jupi 0606X

Scintillator	CsI
Sensitive area	15,4 x 15,4 cm
Pixel dimensions (L=H)	100 x 100 µm
Pixel Number (H x L)	1536x 1536
Voxel Dimension	141 µm
Reconstructed Volume (Diameter x Height)) (max)	105 x 105 mm
Frame rate	20 (1×1) 60 (2×2) > 220 (panoramic

Sensors details for X-View 2D PAN

The X-View 2D Pan can mount 3 different digital sensors for PAN examinations.

Sensor 1

Characteristics	Value
Manufacturer	iRay Technology
Model	Pluto 0600X
Scintillator	CsI
Active area width (H x L)	150 x 7mm
Pixel dimensions (L=H)	100 x 100 µm
Pixel Number (H x L)	1500 x 68
AD Conversion	16 bit
Frame rate (fps) maximum	300 (binning 1x1)
	600m(binning 2x2)
Data interface	GigaE
Trigger mode	Continous or pulsed

Sensor 2

Characteristics	Value
Manufacturer	Teledyne Dalsa
Model	1501
Scintillator	CsI
Active area width (H x L)	149 x 7 mm
Pixel dimensions (L=H)	99 x 99 µm
Pixel Number (H x L)	1505 x 71
Pixel fill factor	85 %
AD Conversion	14 bit
Frame rate (fps) maximum	> 300 (binning 1x1)
	> 600m(binning 2x2)
Data interface	GigaE
Trigger mode	Continuous

Sensor 3

Manufacturer	Athlos
Model	UFS
Scintillator	CdTe
Active area width (H x L)	150 x 5.2 mm
Pixel dimensions (L=H)	100 x 100 µm
Pixel Number (H x L)	1500 x 52
AD Conversion	16 bit
Frame rate (fps) maximum	300 (binning 1x1)
	600m(binning 2x2)
Data interface	GigaE
Trigger mode	Steady Frame Mode Dynamic Frame Modulation TDI Mode
MTF	60%@2lp/mm;

	>30%@5lp/mm
DQE(0)	>80%
TDI scanning object speed (MAXIMUM)	100; 200 cm/s

Sensor for Cephalometric examinations

Characteristics	Value
Manufacturer	iRay Technology
Model	Venu 1012VD
Detector Technology	Amorphous Silicon
Scintillator	CSI
Sensitive area	30 x 25 cm
Pixel dimensions	125 µm
Image format	30 x25 and 25 x 25
Image dimensions (pixel)	2400 x 2000 for 30 x 25 cm image format

V. Indications for Use

The X-View 3D PAN/X-View 2D PAN panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images of examined volume for the reconstruction of 3D view. The X-View 3D PAN/X-View 2D PAN dental panoramic and cephalometric device is intended for general populations as long as they are older than 10 years.

The device must only be operated and used by dentists and other legally qualified professionals.

VI. Comparison Technological Characteristics with the Predicate Device

	Subject Device	Predicate Device	Comparison
Device	**X-VIEW 3D PAN / X-VIEW 2D PAN**	**X-MIND trium**	**NA**
Manufacturer	Trident s.r.l., Italy	de Götzen S.r.l. – Acteon Group Via Roma, 45 21057 Olgiate Olona VA - Italia	NA
510(k) Number	K222666	K160166	NA
Classification & Product Code	892.1750, OAS.	892.1750, OAS.	
Device Classification Name	Computed tomography x-ray system	Computed tomography x-ray system	Same

Regulation Name and Common Name	Computed tomography x-ray system	Computed tomography x-ray system	Same
Indication for Use	The X-View 3D PAN/X-View 2D PAN dental panoramic and cephalometric device is intended for dental radiographic examinations of teeth, jaw and TMJ areas by producing conventional 2D X-ray images as well as X-ray projection images of examined volume for the reconstruction of 3D view. The X-View 3D PAN/X-View 2D PAN dental panoramic and cephalometric device is intended for general populations as long as they are older than 10 years. The device must only be operated and used by dentists and other legally qualified professionals.	X-MIND trium is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in: - producing panoramic X-ray images for diagnostic examination of dentition (teeth), jaws and oral structures; - producing radiographs of maxillofacial region and parts of the skull for cephalometric examination, if equipped with CEPH arm; - producing radiographs of hands and wrists for carpus examination, if equipped with CEPH arm; - producing tomographic images of the oral and maxillofacial region, for diagnostic examination of dentition (teeth), jaws, oral structures and some cranial bones, if equipped with CBCT option.	Similar
Intended Use	Intended for dental radiographic examinations of teeth for general population and to be operated by dentist and other legally qualified professionals.	Intended for dental radiographic examinations of teeth for general population and to be operated by dentist and other legally qualified professionals.	Same

Characteristic	**X-View 2D Pan/X-View 3D PAN**	**X-MIND trium**

	From a clinical point of view, X-View can be applied for the following medical indications: Generic dentistry Dental implantology Dental surgery Maxillo-facial surgery Cephalometric analysis Carpus radiology The target patient populations as long as they are older than 10 years anyway the sustainability to X-ray exposure must be evaluated by surgeons, dentists and qualified and authorized physicians.	From a clinical point of view, X-MIND trium can be applied for the following medical indications: Generic dentistry Dental implantology Dental surgery Maxillo-facial surgery Cephalometric analysis Carpus radiology The target patient population includes adults and pediatric patients from 5 years old [~21 kg (46 lb); 113 cm (44.5 in) standing height]; anyway the sustainability to X-ray exposure must be evaluated by surgeons, dentists and qualified and authorized physicians.
Performance specifications	1) Panoramic 2) Cephalometric (optional) 3) CBCT (optional)	1) Panoramic 2) Cephalometric (optional) 3) CBCT (optional)
Exam mode	1) PAN: - standard panoramic - child panoramic - TMJ - bitewing - sectorial panoramic with improved orthogonality - maxillary sinuses 2) CEPH: - frontal (AP/PA) - lateral (LL) - hand acquisition – carpus (special support needed) 3) CBCT: - full view - extended view	1) PAN: - standard panoramic - child panoramic - TMJ - bitewing - sectorial panoramic with improved orthogonality - maxillary sinuses 2) CEPH: - frontal (AP/PA) - lateral (LL) - hand acquisition – carpus (special support needed) 3) CBCT: - full view - extended view

Flat Panel	Jupi0606X	C12280D-40	Different
Manufacturer Technology	iRay Technology	Hamamatsu Photonics KK	Different

Mode of operation	Continuous operation with intermittent load	Continuous operation with intermittent load	Same

Discussion of the same characteristics

The subject and predicate have some of the same characteristics such as the same classification and product code, same indication for use, same intended use, same mode of operations, panoramic image receptor technology, same readout circuit, scintillator, and same tube cooling method.

Discussion of main differences and secondary predicate

1) Flat panel imager: X-View 3D systems mounts a Flat panel imager supplied by iRay Technology instead of the Hamamtsu used on the predicate. The imager of X-View 3D has the latest construction technology, also if the scintillator screen is the same. This fact will impact on the following items:
    a. Pixel size: 100µ instead the 200µ will allows to have more details on the reconstructed image.
    b. Larger sensitive area will allow a higher FOV.
    c. Pixel numbers of the image are different due to the larger sensitive area and the lower pixel size; this will increase the acquired image size but will give more details on the reconstruction, also increased by the pixel depth (16 bit compared with the 13 bit of the predicate).
    d. The acquisition speed of the proposed device has a multiple mode, allowing the acquisition software to drive the imager at a maximum frame rate.
2) Tube focal spot: X-View systems are using an RX tube having a focal spot of 0.5 according to IEC 60366:2005; the predicate device has a lower focal spot; this difference does not affect the image quality as X-View compensates for this with a lower pixel size. The focal spot of X-View is stated according to the IEC standard requirements.
3) Electrical power line resistance: X-View has a higher one but respects the IEC 60601-1 standard; this will not affect the systems' functionalities.
4) Tube head total filtration: X-View system complies with IEC 60601-1-3, having total filtration higher than the required 3.05 mm AL eq. required at 85 kV.
5) Leakage radiation: X-View respects the IEC standards, so declares a lower leakage radiation than the one required by 21 CFR.
6) Up and down stroke: this data is linked to the mechanical dimensions of the units; X-View has a lower data, but its run is such that it can accommodate all types of patients.

VII. Performance Data

Summary of non-clinical testing and laboratory testing was performed according to the following standards:

Sterilization and Shelf-Life does not apply to the subject device.

Biocompatibility

For the biocompatibility of the parts that can come into contact with the patient, ISO 10993-1:2009 "Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process" has been considered. The system uses plastic components made of material widely used in the medical device field (ABS).

According to the reported standard, no biocompatibility problem has been observed.

Electrical safety and electromagnetic compatibility (EMC) were conducted on the subject device. The subject device complies with the standards for safety that are listed below.

IEC 60601-1:2005/AC1:2006 /A1:2012/AC1:2014: Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance)

- All the requirements of this standard were met, except for inapplicable requirements.
- This standard has not been adapted for application to the device under review.
- Test Reports 10SO00079 identify the requirements of this standard not applicable to the device.
- No deviations from this standard were applied.

IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

- All the requirements of this standard were met, except for inapplicable requirements.
- This standard has not been adapted for application to the device under review.
- Test Reports 80SN00267 identify the requirements of this standard not applicable to the device.
- No deviations from this standard were applied.

IEC 60601-1-3:2008: Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

- All the requirements of this standard were met, except for inapplicable requirements.
- This standard has not been adapted for application to the device under review.
- Test Report 10SN00119 identifies the requirements of this standard not applicable to the device.
- No deviations from this standard were applied.

IEC 60601-1-6:2010+AMD1:2013 and IEC 62366-1:2015: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

- All the requirements of this standard were met, except for inapplicable requirements.
- This standard has not been adapted for application to the device under review.
- No deviations from this standard were applied.

IEC 60601-2-63:2012 (Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment)

- All the requirements of this standard were met, except for inapplicable requirements.
- This standard has not been adapted for application to the device under review.
- Test Report 10SN00119 Annex no.1 identifies the requirements of this standard not applicable to the device.
- No deviations from this standard were applied.

IEC 60825-1 (2007): Safety of laser products - Part 1: Equipment classification and requirements

- All the requirements of this standard were met, except for inapplicable requirements.
- This standard has not been adapted for application to the device under review.

No deviations from this standard were applied.

Software and Risk Analysis

Both acquisition software Deep-View and Archimed Suite have already been FDA cleared with other devices (ref. to K162619, K160386, K200625); Archimed Suite has also been cleared by another manufacturer (K211688). The version used for this clearance is equal to the above cleared versions with the upgrade related only to digital sensor interface, where specific drivers supplied by the sensor manufacturer have been included.

Software architecture of X-VIEW PAN can be divided into two groups:

- Main unit software. This software will be designated, in the following, as “Main firmware” and is embedded on the system.
- Software running on dedicated image acquisition PC, using standard “Windows®” Operating System; it has been validated for Windows. It is referenced as “Acquisition software”, or “Acquisition software control” or “X-VIEW interface”.

The dedicated software for image acquisition is running on a dedicated PC.

Main firmware

The Main firmware and the Acquisition software do not perform any diagnosis; the mitigation actions are not committed to the Main firmware or to the Acquisition software, so a failure in Main firmware and/or Acquisition software result in a Minor Injury, either to a patient or to a user of the device.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."* The software for this device was considered as a "Moderate" level of concern since a malfunction of, or a latent design flaw in the device software can lead to an erroneous diagnosis or a delay in delivery of appropriate medical care.

Risk Analysis Information

A risk analysis study according to ISO 14971 has been carried out on the entire system and takes into account also the software-related risks. All aspects of the X-View system have been evaluated or mitigated and all final test results are a PASS.

The analysis of the benefit / risk ratio related to the execution of radiological investigations is left to the discretion of the end user, who is a doctor or dentist radiologist and is therefore able to evaluate this relationship.

The petition was prepared in compliance with the following FDA guidance instructions and documents: *"Guidance for the submission of 510(k) for Solid State X-ray Imaging Devices".* Also, the *"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices".*

Performance

The following performance data is provided in support of the substantial equivalence determination. All tests performed are included in this submission.

Software … the level of concern for this device is MODERATE.

Performance Testing…was completed as a direct comparison between the subject and predicate device.

Clinical tests were performed both in Italy at the University of Genoa and the clinical judgment made by ABR, President of Dental Imaging Consultants, LLC, have demonstrated the clinical validity of the X-View systems both in the execution of PAN-type exams and 3D volumetric exams. Images were presented and approved by the ABR Consultant.

Conclusion

The comparison of intended use and technological characteristics shows the subject device is at **least as safe and effective** as the predicate, and, furthermore, warrants a finding of substantial equivalence between the subject device, X-VIEW 3D PAN/X-VIEW 2D PAN and the predicate device, Panoura X-ERA NLFNF/MF. Furthermore, this finding of substantial equivalence warrants clearance from FDA for marketing activities in the United States.