de Götzen S.r.l
℅ Dario Bandiera
Quality Manager
via Roma, 45
21057 Olgiate Olona, Varese
ITALY

February 20, 2020

Re: K191719
Trade/Device Name: X-MIND Trium
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: January 10, 2020
Received: January 22, 2020

Dear Dario Bandiera:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191719

Device Name
X-MIND trium

Indications for Use *(Describe)*

Indications for Use (Describe)

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.

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.

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.

Index

510 (k) Summary

The summary of this 510(k) is being submitted in accordance with the requirements of 21 CFR Part 807.92.

I. SUBMITTER

Owner's name:	de Götzen S.r.l. – ACTEON Group
Address:	via Roma, 45 – 21057 Olgiate Olona (VA), Italy
Tel.	+39 0331 376760
Fax	+39 0331 376763
Dario Bandiera	dario.bandiera@acteongroup.com
Alvise Reither	alvise.reither@acteongroup.com
Date:	10/01/2020

Table 1: Submitter information

II. DEVICE

Name of the device:	X-MIND trium
Common or Usual name:	Dental panoramic, cephalometric and CBCT X-ray system
Classification name:	Computed tomography X-ray system (21 CFR 892.1750)
Regulatory class:	II
Product Code:	OAS, MUH

Table 2: device

III. PREDICATE DEVICE

Legally marketed device to which equivalence is claimed is:

PREDICATE DEVICE	
Device name	X-MIND trium
Manufacturer	de Götzen S.r.l. – ACTEON Group
Device product code	OAS
Subsequent product code	MUH
Regulation number	892.1750
Regulation name	Computed tomography x-ray system
Clearance date	November 15, 2016
510(k) number	K160166

Table 3: Predicate device information

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

No reference devices were used in this submission.

IV. DEVICE OVERVIEW

The modified X-MIND trium has the same indication for use of X-MIND trium (as identified in the labelling) and it is based on the same fundamental scientific technology.
It 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.

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.

V. MAIN CHANGES TO THE PREVIOUS CLEARED DEVICE ARE

Main changes to the previous cleared device are addition of a new accessory: new sliding cassette called X-MIND trium TLD cassette including a new model of CBCT sensor (C12903D-40 - Hamamatsu) that can be used for both panoramic and CBCT examination; introduction, as alternative components, of CEPH and PAN sensors with wider admitted range of power supply value: (from 4.9 – 5.1 VDC to 8 – 12 VDC).

Since CBCT and PAN sensor usually operates on a different SID (Source to Image Distance), a new movement of the cassette has been added, to give to the device the possibility to modify the SID.

The possibility to configure the SID allows also the possibility to perform special exam for child: reduced SID distance that means possible reduction of x-ray dose to the patient.

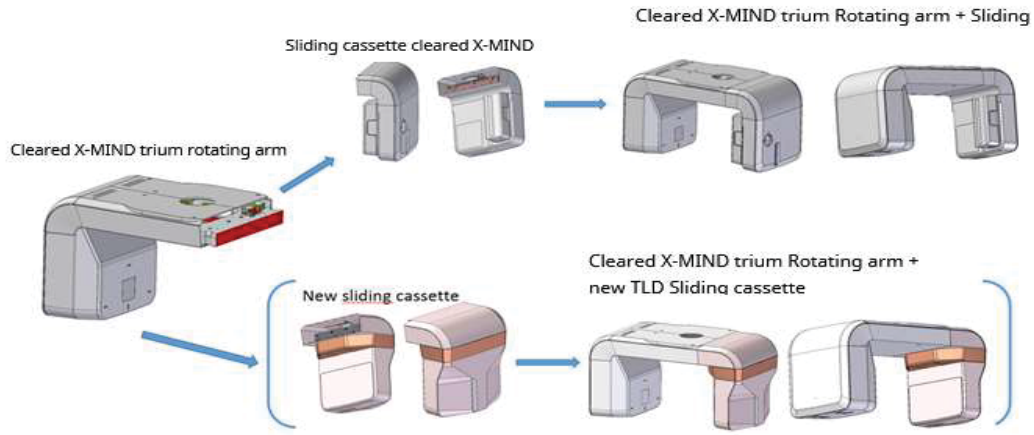


Figure 1 addition of TLD Sliding cassette

The lateral movement of the cassette is obtained with the same motor used in the cleared version of X-MIND trium.

For the movement we use a new linear guide with ball bearing runners.

The SID movements uses the same motor as the one installed in the handle rest area of the patient (satellite group), and two linear guides with ball bearing runners as the cleared version of TRIUM

The cassette is made of a steel plate with the new CBCT sensor and relevant shielding lead on the back.

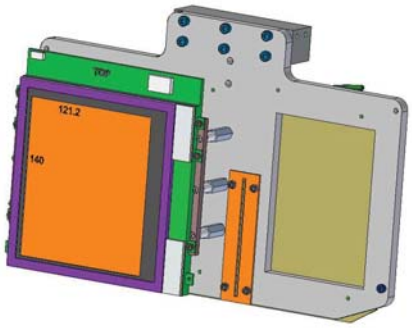


Figure 2: new TLD cassette scheme

The new CBCT sensor has nominal dimensions of 15x12 cm, while the sensor used in cleared version of X-MIND trium is 12x12.

The 15 cm height is required to allow panoramic examinations.

The new sensor C12903D-40 has 8V power supply input while the previous was 5V. Similarly, the new SID movements require a related driver. For that reason, a new AUXCBCT board has been designed with code: PE5541_AUXCBCTPLUS.

The overall insulation diagram of the whole device has not changed in respect of the cleared X-MIND trium, apart from the absence of the contacts for PAN and CEPH sensors that aren't anymore detachable (improvement)

The relevant insulation of the board PE5541_AUXCBCTPLUS_A01 is the same as the PE4016_AUXCBCT_A04, already installed (and certified) on the V1 version of the TRIUM.

Due to the possibility to reduce the SID, special exams for child has been introduced and at the same time we have developed countermeasures to avoid that an adult is positioned during a special child exam.

The new workflow on the software introduces a new step: the doctor uses a tool provided with the machine to check if the user fits the proper dimension for the examination with the reduced SID.

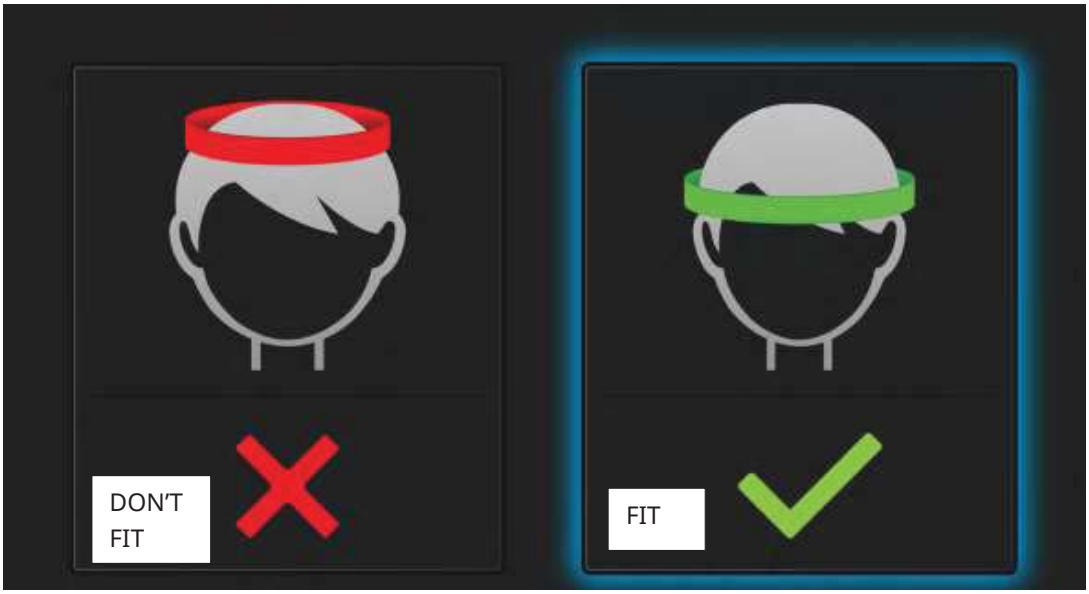


Figure 3: use of head measurement tool

X-MIND trium and the X-MIND trium TLD are provided with a new functionality, the Low Dose functionality.

The Low Dose functionality allows the user to perform the CBCT exams by using the Low Dose protocols for all kind of patients (MAN, WOMAN and CHILD) as an alternative of the Standard Dose protocols.

The selection of a Low Dose protocol is performed in the AIS interface during the specification of the exam settings (see Figure 4).

A Low Dose protocol applies at least the half of the anodic current than the corresponding Standard Dose protocol, so ensuring a radiation dose saving for the patient of about 50% (refer to the declared DAP in the AIS interface, Figure 5); the image quality by the Low Dose protocols ensures the same diagnostic value as the corresponding Standard Dose protocols (Basing on the bench test results on image quality and radiation dose obtained).

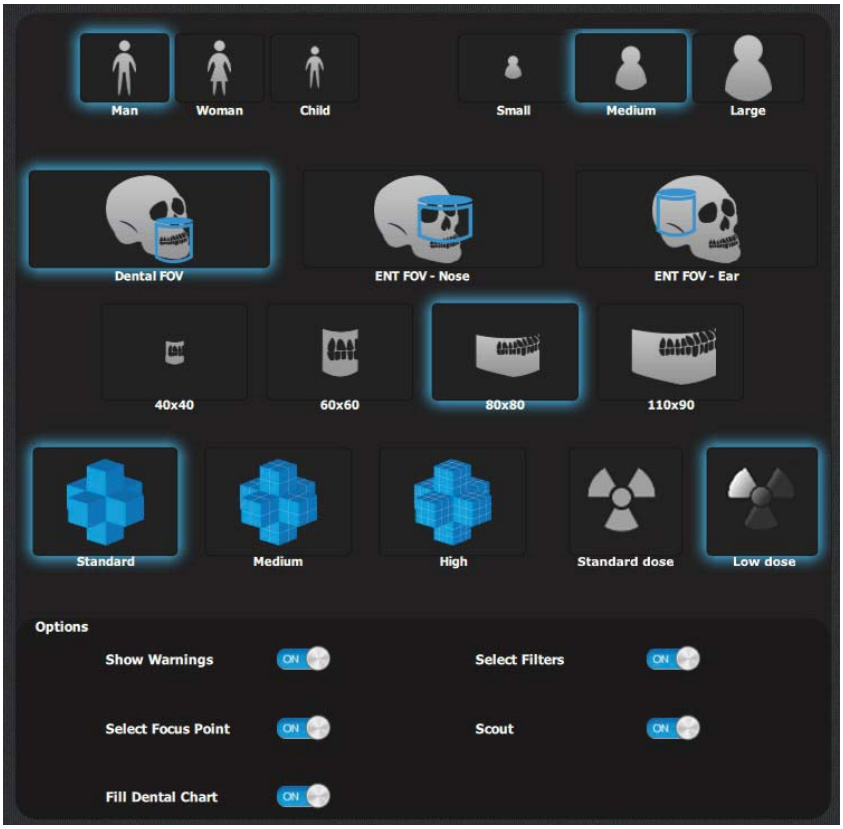


Figure 4 - AIS interface for the definition of the Low Dose protocol

Figure 5 - Acquisition parameters and dose declaration between Standard Dose and Low Dose protocols

VI. OVERVIEW OF THE SYSTEM

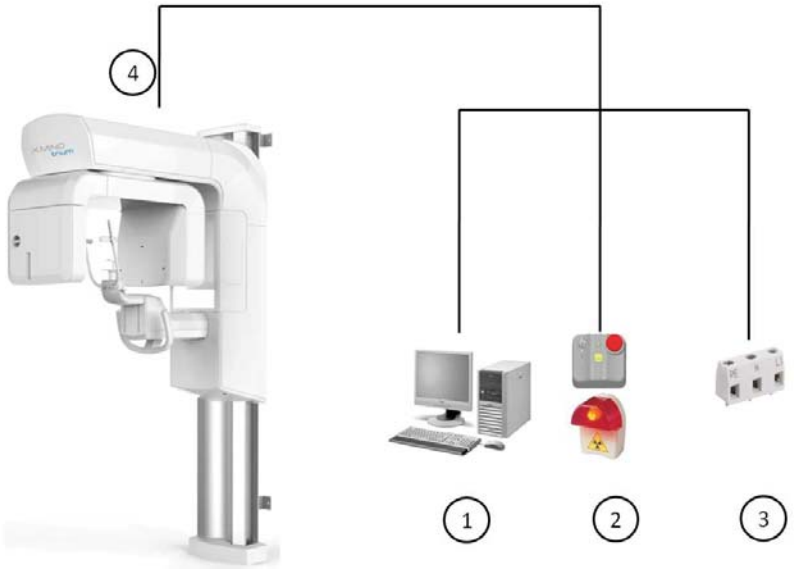


Figure 6: overview of the system

Part 1		- 1 Gb, 8-wire Ethernet cable cat. 6>250mhz, 27 AWG, 10 m long - Operator's Workstation
Part 2		- Control cable, 10 wires, 5 twisted pairs 10 m long aluminium shielded - X-MIND trium Remote Control - X-MIND trium Light
Part 3		- Power cord, 3G1,5 AWG 16, 300 / 500 V, 10 m long -Connection to the mains by means of clamps and screws (Equipment installed permanently in compliance with IEC 60601-1)

Part 4		- X-MIND trium main connector consisting of 3 modules Communication, control and power supply - Moving part of the X-MIND trium connector - Fixed part of the X-MIND trium connector

Table 4: details of the system

The system consists of:

- X-MIND trium SCANNER
- OPERATOR'S WORKSTATION

The operator can control all aspects of the medical device by means of the workstation that can be supplied by de Götzen.

The workstation must have installed with the following modules:

- **AIS** equipment management software + **AIS 2DApp** diagnostic analysis
- **AIS 3DApp** dataset display software CBCT

Communication with the medical device occurs by means of a sturdy and reliable Ethernet protocol.

The workstation allows the operator to perform the following procedures:

- Calibrations of the medical device
- Acquisition parameters setting
- Getting an acquisition
- Image visualization and post processing
- Database management
- Periodic quality Tests

- X-MIND trium REMOTE CONTROL

The X-MIND trium remote control must be in a safe place protected against radiations, in compliance with the local standards in force concerning ionising radiation protection.

The X-MIND trium remote control allows the operator to activate or deactivate X-ray emission from the control room. This consists of two switches, one for exposure and one for emergency, which control device operation.

- X-MIND trium Light

The X-MIND trium Light is an indicator light that warns that X-ray emission is in progress.

VII. OVERVIEW OF THE SCANNER

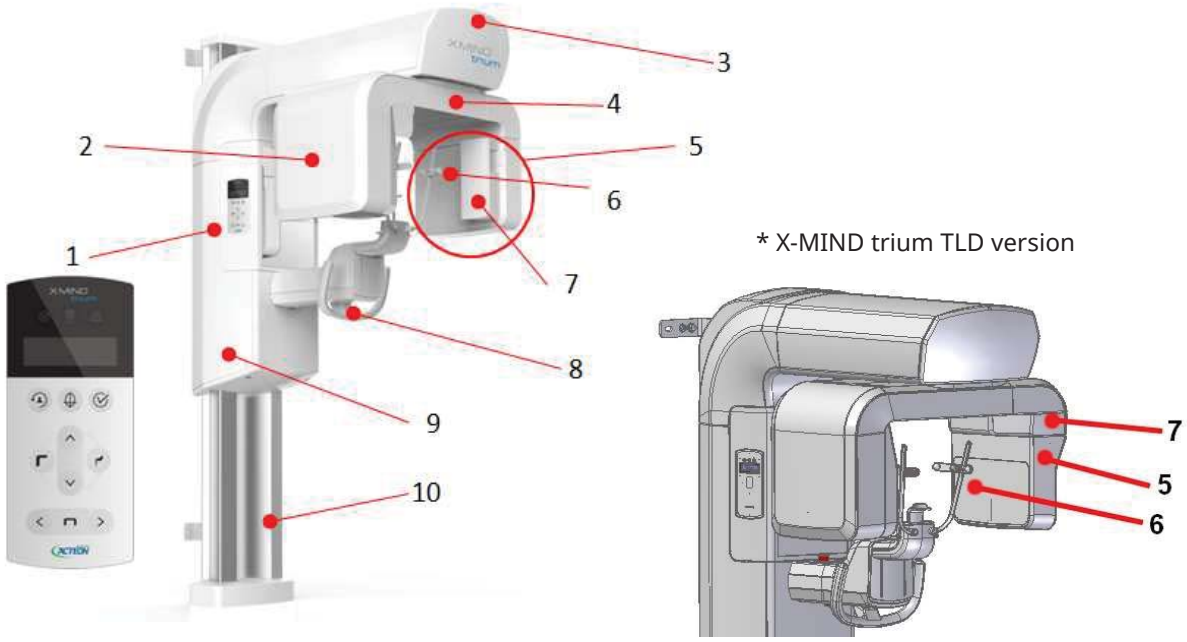


Figure 7: overview of the scanner

The X-MIND trium scanner consists of the following parts:

1	Control panel	The control panel provides an intuitive overview of the system to move the mobile column, turn the positioning lasers on and off and activate the X-MIND trium medical device.
2	X-ray generator	The X-ray assembly is the source of the X-ray beam during the rotation of the U-Arm. The pulsed beam is modelled by an automatic collimator, whereas the electronic control ensures stability and accuracy of the selected loading factors (exposure time, kVp and anodic current). An aluminium filter is used to harden the beam and remove low-energy ionising radiations, thereby obtaining suitable radiation quality whilst reducing its dose absorbed by the patient.
3	Sliding body	The sliding body is the mobile part of the column that supports U-arm.
4	U-arm	The U-Arm supports the Detector sliding group and the X-ray generator. This is the rotating part of the medical device, which moves around the patient during the image acquisition phase.
5	Detector sliding group	It contains detectors that allow acquire images. This cassette can be provided in the following versions: • PAN Only cassette; • Standard PAN/ CBCT Cassette; • TRUE LOW DOSE cassette that permit to perform both PAN and CBCT exams. (* only with X-MIND trium TLD version)
6	CBCT detector	This flat panel detector is indicated for use in generating radiographic images of the maxillo-facial region, more specifically it is dedicated for CBCT acquisitions. in X-MIND trium TLD version there is only one image detector, for PAN and CBCT exam; the equipment automatically exposes in front of X-Ray source the right portion of detector, depending on the selected exam;
7	PAN detector	This flat panel detector is indicated for use in generating radiographic images of the maxillo-facial region, more specifically it is dedicated for PAN acquisitions.

		* in X-MIND trium TLD version there is only one image detector, for PAN and CBCT exam; the equipment automatically exposes in front of X-Ray source the right portion of detector, depending on the selected exam;
7	TLD CASSETTE*	* only for X-MIND trium TLD version Sliding cassette that lets to activate true low dose exams. Some models of X-MIND trium can be upgraded in the field to TLD cassette configuration.
8	Patient support	The patient support allows stabilising and immobilising the patient. It is equipped with instruments to move the patient's head in all directions and find the best superimposition between the patient's anatomy and the Field of View (FOV).
9	F group	It is the whole assembled mobile group of the device. It is the moving part of the medical device, which adapts the acquisition geometry to the patient's anatomy and stance (sitting or standing). It supports the U-Arm and head support.
10	Column	The fixed column supports the entire structure of the medical device. This contains the motor that raises and lowers the mobile column, the main control panel of the system and the main switch. In the wall installation version, the fixed column is equipped with an anchor plate; in the free-standing version, on the other hand, the medical device is equipped with a footrest. *CEPH* arm extension (not represented in Overview of the medical device)

Table 5: scanner parts

The ceph arm extension can be positioned both on the right or left side of the vertical column, with the patient positioning aiming device (ear and nasion rest) for CEPH exams;

the CEPH secondary collimator, translating during X Rays (to stay aligned with the X-Ray beam emerging from the tubehead on overhead carriage);
the CEPH image detector, translating during X Rays (to stay aligned with the X-Ray beam emerging from the secondary collimator on the CEPH arm itself)

VIII. EQUIPMENT CONFIGURATIONS

X-MIND trium equipment can be sold in these different configurations:

PAN only

the equipment can carry out uniquely exams of the PAN group (PAN, TMJ, Sinus);
the image detector is not movable from PAN bay;
all the exams are carried out with the same extension in height (146mm height on image receptor), primary collimator being of fixed dimension;
the equipment can be upgraded in the field to more advanced configurations

PAN / CBCT

the equipment can carry out uniquely exams of the PAN group (PAN, TMJ, Sinus) and of the CBCT group;
there are two image detectors, one for PAN and one for CBCT exam; the equipment automatically exposes in front of X-Ray source the right detector, depending on the selected exam;
the PAN exams can be carried out with different extension in height (up to 146mm height on image receptor), primary collimator being automatically adjusted in height, depending on exam selected by the user:
the CBCT exams can be carried out at different FOV dimensions;
the equipment can be upgraded in the field to PAN/CEPH/CBCT configuration by simple procedure, adding CEPH arm with CEPH image detector replacing the existing PAN image detector;
the equipment has a touch screen panel as main user interface;

PAN / CEPH

the equipment can carry out uniquely exams of the PAN group (PAN, TMJ, Sinus) and of the CEPH group (AP/PA, LL, carpus);

the image detector is unique, both for PAN and CEPH exams, and must be manually moved from PAN bay to CEPH bay and viceversa, depending on the selected exam;

the exams can be carried out with different extension in height (up to 146mm height on image receptor for PAN, up to 220mm height on image receptor for CEPH), primary collimator being automatically adjusted in height depending on exam selected by the user;

the equipment can be upgraded in the field to PAN/CBCT/CEPH configuration by simple procedure, adding CBCT image detector and bite block holder with vertical movement;

the equipment mounts PAN detector sliding unity.

PAN / CBCT / CEPH (PAN Full)

the equipment can carry out all feasible exams of the PAN group (PAN, TMJ, Sinus), of the CEPH group (AP/PA, LL, carpus) and of the CBCT group;
there are two image detectors, one for PAN/CEPH and one for CBCT exam; to carry out PAN or CEPH exam the PAN/CEPH image detector must be manually moved from PAN bay to CEPH bay and viceversa;
to carry out PAN or CBCT exam the equipment automatically exposes in front of X-Ray source the right detector, depending on the selected exam;
the PAN and CEPH exams can be carried out with different extension in height (up to 146mm height on image receptor for PAN, up to 220mm height on image receptor for CEPH), primary collimator being automatically adjusted in height depending on exam selected by the user;
the CBCT exams can be carried at different FOV dimensions;
the equipment has a touch screen panel as main user interface;

PAN / CBCT TLD version

The equipment can carry out both exams of the PAN group (PAN, TMJ, Sinus) and of the CBCT group;
There is only one image detector, for PAN and CBCT exam; the equipment automatically exposes in front of X-Ray source the right portion of detector, depending on the selected exam;
PAN exams can be carried out with different extension in height (up to 146 mm height on image receptor), since the collimator height can be adjusted depending on the exam selected by the user;
CBCT exams can be carried out at different FOV dimensions;
The equipment can be upgraded in the field to CEPH configuration by simple procedure, adding CEPH arm with CEPH image detector.

PAN / CBCT / CEPH TLD version

The equipment can carry out all feasible exams of the PAN group (PAN, TMJ, Sinus), of the CEPH group (AP/PA, LL, carpus) and of the CBCT group;
To carry out PAN or CEPH or CBCT exam the equipment automatically exposes in front of X-Ray source the right detector, depending on the selected exam;
PAN and CEPH exams can be carried out with different extension in height (up to 146 mm height on image receptor for PAN, up to 220 mm height on image receptor for CEPH), since the primary collimator can be automatically adjusted in height depending on exam selected by the user;

the image detector is not movable from CEPH bay;

CBCT exams can be carried out at different FOV dimensions;

IX. EXAMS

In its different configurations X-MIND trium equipment carries out the following exams (also said projections):

PAN group

- Standard panorama
- Child special SID panorama (only with TLD cassette)
- TMJ
- Bitewing
- Sectorial
- Maxillary sinuses

CBCT type

- Full view
- Extended view (TBC)
- Stitched (TBC)
- Child special SID CBCT (only with TLD cassette)

CEPHALOGRAPHIC type

- Frontal
- Lateral
    - Child lateral (reduced height and width) (non c'è nel manuale)
    - Complete lateral (non c'è nel manuale)
- Hand acquisition (special support needed)

X. Setup configuration

Wall mounted

For this type of installation, the column is provided with two dedicated plates to fasten the equipment to the wall.

Figure 8: wall mounted configuration

1	2 expansion anchors
2	2 expansion anchors

Self-standing

The self-standing accessory allows to install X-MIND trium without structurally fix it to the wall; the self-standing alone is designed to give full structural support to X-MIND trium for installation where the walls do not guarantee such support.
Although self-standing is sufficient to provide alone the needed structural support to X-MIND trium, it is anyway highly recommended to fix the X-MIND trium also to the wall, to reduce as much as possible the vibrations during the exams; this wall fixation has not safety implications, so it is responsibility of the customer to use it or not.

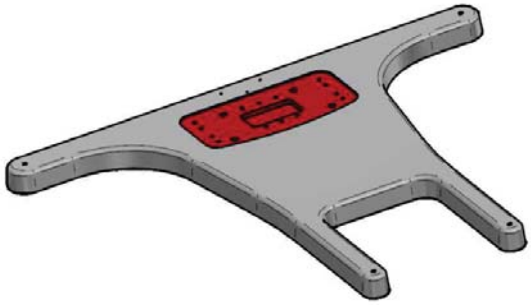


Figure 9: wall mounted base

XI. ACCESSORIES

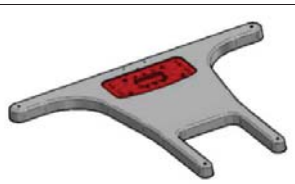
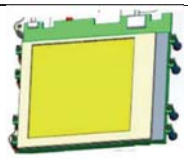
XMT SELF STANDING BASE (FWT)	
XMT REMOTE BUTTON	
EXTERNAL LIGHT 100 – 240 V	
XMT CARPUS SUPPORT	
XMt UPG CEPH	
XMt UPG 3D	
XMt TRUE LOW DOSE CASSETTE	

Table 6: accessories

XII. CONFIGURATIONS

○ upgadable on site

TRUE LOW DOSE

XIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
Manufacturer	de Götzen S.r.l. – Acteon Group Via Roma, 45 21057 Olgiate Olona VA - Italia	de Götzen S.r.l. – Acteon Group Via Roma, 45 21057 Olgiate Olona VA - Italia	same
510 (k) number	K160166		
Indication for use	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;	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;	same

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
	- 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.	- 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.	
Performance specifications	1) Panoramic 2) Cephalometric (optional) 3) CBCT (optional)	1) Panoramic 2) Cephalometric (optional) 3) CBCT (optional)	same
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)	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)	same

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
	3) CBCT: - full view - extended view	3) CBCT: - full view - extended view	
Type of power supply	Single-phase alternating current power supply	Single-phase alternating current power supply	same
Nominal voltage	100 V - 240V	100 V - 240V	same
Maximum voltage variation	±10%	±10%	same
Nominal current	7 A (@ 240 V) 15 A (@ 100 V)	7 A (@ 240 V) 15 A (@ 100 V)	same
Frequency	50 - 60 Hz	50 - 60 Hz	same
Operation mode	Continuous operation with intermittent X-ray loading	Continuous operation with intermittent X-ray loading	same
Protection against electrical shock	Class I	Class I	same
Degree of protection against electrical shock	Type B	Type B	same
Emission	Group 1, Class A	Group 1, Class A	same
Manufacturer of the X-ray tube	Skan X	Skan X	same
X-ray tube model	CEI OPX/105	CEI OPX/105	same
Nominal High Voltage	60 - 85 kV for PAN/CEPH	60 - 85 kV for PAN/CEPH	same

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
	80 - 90 kV for CBCT	80 - 90 kV for CBCT	
Anode heat storage capacity	30 kJ	30 kJ	same
Nominal focal spot diameter	0.5 mm	0.5 mm	same
Anode material	Tungsten	Tungsten	same
Target Angle	5°	5°	same
Anodic current	4 – 10 mA for PAN/CEPH 4 – 10 mA for CBCT	4 – 10 mA for PAN/CEPH 4 – 10 mA for CBCT	same
Total filtration	2.8 mm Al for PAN/CEPH at 85 kV 7.0 mm Al for CBCT at 90 kV	2.8 mm Al for PAN/CEPH at 85 kV 7.0 mm Al for CBCT at 90 kV	same
HVL	3.4 mm Al for PAN/CEPH at 85 kV 5.2 mm Al for CBCT at 90 kV	3.4 mm Al for PAN/CEPH at 85 kV 5.2 mm Al for CBCT at 90 kV	same
High Voltage	kV ± 10%	kV ± 10%	same
Current in the tube	mA ± 20%	mA ± 20%	same
Exposure time seconds	Seconds ± (5% + 50ms)	Seconds ± (5% + 50ms)	same
Detector technology	CMOS	CMOS	same
Detector manufacturer	Hamamatsu	Hamamatsu	same

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
Detector model	PAN: C10500D-42 CBCT: C12280D-40 CEPH: C10502D-42	PAN: C10500D-70 PAN/CBCT: C12903D-40G (TLD) CEPH: C10502D-70	1 3 2
Pixel size	100 µm	100 µm	same
Typical image size	PAN: 1480 px x 2658 px (C10500D-42) CEPH: 2232 px x 2673 px (C10502D-42)	PAN: 1480 px x 2658 px (C10500D-70) PAN: 1400 px x 2658 px (C12903D-40G) CEPH: 2232 px x 2673 px (C10502D-70)	1 3 2
Active area	PAN: 148 mm x 6 mm (C10500D-42) CBCT: 121.6 mm x 123.2 mm (C12280D-40) CEPH: 220 mm x 6 mm (C10502D-42)	PAN: 148 mm x 6 mm (C10500D-70) PAN: 140 mm x 6 mm (C12903D-40G) CBCT: 139.2 mm x 121.2 mm (C12903D-40G) CEPH: 223,2 mm x 6 mm (C10502D-70)	1 3 3 2
Theoretical detector	4.5 lp/mm	4.5 lp/mm	1, 2
Actual in imaging[1]	4.5 lp/mm	4.5 lp/mm	1, 2
Image resolution[2]:	PAN: high contrast resolution: 3.1 lp/mm PAN: low contrast resolution: Four holes are visible	PAN: high contrast resolution: 3.1 lp/mm PAN: low contrast resolution: Four holes are visible	1 1

[2] Resolution data are taken from results of bench test performed on both devices (See section 15 Bench tests)

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
	CEPH: high contrast resolution: 3.1 lp/mm CEPH: low contrast resolution Four holes are visible	CEPH: high contrast resolution: 3.1 lp/mm CEPH: low contrast resolution Four holes are visible	2 2
X-ray exposure time	PAN: 16.8 s CEPH:18 s	PAN: 16.8 s CEPH:18 s	1 2
Detector technology	Flat panel CMOS	Flat panel CMOS	same
Detector manufacturer	Hamamatsu	Hamamatsu	same
Detector model	C12280D-40	C12903D-40G	3
Image voxel size	75 µm (minimum slice thickness)	75 µm (minimum slice thickness)	3
FOV (diameter x height)	40 mm x 40 mm 60 mm x 60 mm 80 mm x 80 mm 110 mm x 80 mm	40 mm x 40 mm 60 mm x 60 mm 80 mm x 80 mm 80 mm x 90 mm 110 mm x 80 mm 110 mm x 90 mm	3, 4
Detector resolution[2]:	High contrast resolution: V10%: 2.07 lp/mm: High contrast resolution: V50%: 0.72 lp/mm	High contrast resolution: V10%: 2.81 lp/mm: High contrast resolution: V50%: 0.95 lp/mm	3

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
Rotation	360°	360°	same
Scanning time	12 s to 30 s maximum	12 s to 30 s maximum	same
X-ray real exposure time	6s (Normal quality) 7.2s (Medium quality) 9s (High quality)	6s (Normal quality) 7.2s (Medium quality) 9s (High quality)	same
Source Image Distance (SID)	PAN: 550mm CBCT: 633mm	PAN: 550mm (adult) PAN: 490mm (special small child) CBCT: 610 (adult) CBCT: 588 (special small child)	4
Protocol types (CBCT exams only)	Standard Dose protocols	Standard Dose protocols Low Dose (LD) protocols	7
Dimensions	Footprint: PAN/CBCT: max 1100 mm x 1505 mm With CEPH: max 1715 mm x 1500 mm Height: 2350 mm	Footprint: PAN/CBCT: max 1100 mm x 1505 mm With CEPH: max 1715 mm x 1500 mm Height: 2350 mm	same
Weight	PAN: 230 kg PAN/CBCT: 240 kg PAN/CBCT With CEPH: 280 kg	Wall mount: PAN: 230 kg PAN/CBCT: 240 kg PAN/CBCT With CEPH: 280 kg Self standing: PAN: kg 280	6

Characteristic	Predicate	Proposed	Change Id
	X-MIND trium	X-MIND trium	
		PAN/CBCT: kg 290 PAN/CBCT With CEPH: kg 330	
Mechanical configuration	Wall mount	Wall mount Self standing	6
Patient position	Standing, seated or on wheel-chair	Standing, seated or on wheel-chair	same

Table 7 Comparison between proposed and predicate devices.

Both X-MIND trium and X-MIND trium TLD are digital panoramic, cephalometric and tomographic extra-oral X-ray systems. For analysis of patients' images, X-MIND trium can be provided with a dedicated workstation which has the following modules installed:

- ACTEON IMAGING SUITE (AIS) + 2D diagnostic analysis
- AIS 3D app for CBCT dataset only (clearance K173041)

The 2D diagnostic analysis and the AIS 3D app (CBCT) provide a complete set of tools for visualization and post-processing of 2D radiographs (such as Panoramic, Cephalometric and Carpus radiographs) and 3D CBCT datasets.

AIS 3D app also includes special features for computer aided dental implant planning.

X-MIND trium TLD introduce a new SID movement (source to image distance) and the possibility to perform both CBCT and PAN exam with the same flat panel. In order to support his new movement and cassette a new version of AUXCBCT board, AUXCBCT Plus, has been developed with the related firmware,

X-MIND trium software is described in detail in Section 13 of this submission.

The following summary table shows a comparison of the functionalities for image processing, enhancing and visualization available in X-MIND trium cleared version and new version that includes LD functionality

This comparison is to provide evidence of substantial equivalence between the tools and means made available by both software module.

Please note that 3D functionality are now covered by clearance K173041

Software characteristic	X-MIND trium 2D analysis + AIS 3D app	X-MIND trium 2D analysis + AIS 3D app	Change Id
Supported Image format	DICOM, JPEG, BMP, TIFF, GIFF, PNG, DGI (proprietary format)	DICOM, JPEG, BMP, TIFF, GIFF, PNG, DGI (proprietary format)	same
Functionalities and features for 2D images: single 3D tomographic sections, panoramic and cephalometric radiographs			
Basic image visualization features	+ Zoom and pan + Rotation + Flipping / mirroring, vertical / horizontal	+ Zoom and pan + Rotation + Flipping / mirroring, vertical / horizontal	same
Measuring function	+ Measuring distances + Measuring angles + Adding annotation + Viewing Pixel profile	+ Measuring distances + Measuring angles + Adding annotation + Viewing Pixel profile	same
Visualization filters	+ Gamma filter + Sharp filter + Equalize filter + Emboss filter + Reverse filter	+ Gamma filter + Sharp filter + Equalize filter + Emboss filter + Reverse filter	same

Pseudocolour analysis LUTs	+ Gray + Inverse Spectrum	+ Gray + Inverse Spectrum	same
Windowing	+ Contrast-brightness set + Lower-Upper level + SHS optimal windowing	+ Contrast-brightness set + Lower-Upper level + SHS optimal windowing	same
Reporting	Included	Included	same
Functionalities and features for CBCT 3D dataset			
Basic image visualization features	+ Zoom and pan + Rotation + Flipping / mirroring, vertical / horizontal	+ Zoom and pan + Rotation + Flipping / mirroring, vertical / horizontal	same
Measuring function	+ Measuring distances + Measuring angles + Adding annotation + Viewing Voxel profile + Measuring polygon + Measuring volumes + Measuring distance on 3D	+ Measuring distances + Measuring angles + Adding annotation + Viewing Voxel profile + Measuring polygon + Measuring volumes + Measuring distance on 3D	same
Processing filters	+ Sharp filter	+ Sharp filter	same

	+ Median filter + SHARP filter: denoiser and edge enhancer + STAR filter: streak and metal artifacts reduction	+ Median filter + SHARP filter: denoiser and edge enhancer + STAR filter: streak and metal artifacts reduction	
Multi Planar Reconstruction (MPR)	+ Axial plane + Coronal plane + Sagittal plane	+ Axial plane + Coronal plane + Sagittal plane	same
Oblique MPR	Included	Included	same
Single and multiple cross sections visualization	Included + Setting number of sections + Setting distance of sections	Included + Setting number of sections + Setting distance of sections	same
Windowing	+ Contrast-brightness set + Lower-Upper level + Editing preset	+ Contrast-brightness set + Lower-Upper level + Editing preset	same
Display mode	+ MPR (voxel intensity) + Ray Sum + Maximum intensity projection (MIP) + Minimum intensity projection (minMIP) + SCOUT	+ MPR (voxel intensity) + Ray Sum + Maximum intensity projection (MIP) + Minimum intensity projection (minMIP)	same

	+ Volume thickness selection (for MIP and Ray Sum)	+ SCOUT + Volume thickness selection (for MIP and Ray Sum)	
3D volume rendering	+ Preset template + Editing of user-defined template	+ Preset template + Editing of user-defined template	same
Surface Rendering	+ Surface generation + STL export	+ Surface generation + STL export	same
Curve Planar Reformation (CPR) for dental analysis	+ Dentascan wizard	+ Dentascan wizard	same
Advanced 3D visualization tools	+ 3D clipping: 3D cut by orthogonal planes + 3D thin slab rendering + 3D sculpting: 3D cut by user-defined planes + 3D flying mode: 3D virtual endoscopy	+ 3D clipping: 3D cut by orthogonal planes + 3D thin slab rendering + 3D sculpting: 3D cut by user-defined planes + 3D flying mode: 3D virtual endoscopy	same
Advanced 3D functions	+ Implant planning wizard + Nerve tracing + Importing 3D STL object in patient volume + STL implant library + Measuring bone density at implant sites	+ Implant planning wizard + Nerve tracing + Importing 3D STL object in patient volume + STL implant library	same

	+ Bone/tissue removal	+ Measuring bone density at implant sites + Bone/tissue removal	
General purpose functionalities			
Screenshot capture function	Image capture (AIS 3D app) 2D analysis module (Export)	Image capture (AIS 3D app) 2D analysis module (Export)	same

Table 8: comparison between Acteon Imaging Suite and predicate device software.

The above tables show that the two devices have the same intended use.

We have conducted the risk analysis and the necessary verification and validation activities to demonstrate that the design outputs of the modified device meet the design input requirements according to our design and development procedure in compliance with 21 CFR § 820.30 and design control guidance for medical device manufacturers.

The impact of the modification on the device and its components on the risk has been evaluated Re-applying Fault Tree Analysis (FTA) and identifying additional events that can generate undesired consequences (top events) originally identified with Preliminary Hazard Analysis (PHA).

Change in detectors have been verified following “Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices”

Bench testing was used to evaluate the trade-off between the image quality and radiation dose of the images obtained with dose reduction due to addition of two main aspects:

1) TLD cassette (when using special exam for child)
2) Low Dose functionality, CBCT mode only

Based on the bench test results on image quality and radiation dose obtained with X-MIND trium cleared device and X-MIND trium proposed device (with TLD cassette and separately with Low Dose functionality), we can assume that the clinical performance obtained with the above changes is equal or better than the ones of the predicate device; these results, confirm the equivalence of X-MIND trium proposed device to X-MIND trium predicate device.

Id	Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
1	New PAN detector	**21A.** Ionising radiation hazard Harm: biological effects due to X-ray ionising radiation due to event 4) Unwanted x-ray exposure due to poor image quality (inadequate for diagnostic purpose)	Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices"	Same technology DQE values for new detector are in the range ±0.1 on the whole frequency range (1 – 4 LP/mm)	Same PASS
2	New CEPH detector	**21A.** Ionising radiation hazard Harm: biological effects due to X-ray ionising radiation due to event 4)	Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices"	Same technology DQE values for new detector are in the range ±0.1 on the whole frequency range (1 – 4 LP/mm)	Same PASS

[3] Complete results are available in substantial equivalence discussion section 11 and in specific reports of V&V and bench tests available in sections 15, 16

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
			Unwanted x-ray exposure due to poor image quality (inadequate for diagnostic purpose)			
3	New PAN-CBCT detector	New detector	**21A.** Ionising radiation hazard Harm: biological effects due to X-ray ionising radiation due to event 4) Unwanted x-ray exposure due to poor image quality (inadequate for diagnostic purpose)	Bench test according to same protocol used in X-MIND trium Submission K160166	Same or superior trade-off between dose and image quality (i.e. System Indicator (SI) in CBCT) $S_{DAP} \geq S_{DAP\ predicate}$ $S_{DAP}=\frac{CNR}{DAP\left(\frac{1}{2\cdot V_{50\%}}\right)^2}$, CNR is the contrast to noise ratio (overaged value from 5 measurements) DAP is the dose area product declared in IFU V50% is the resolution indicator at 50% modulation	Woman Medium Standard quality FOV 80X80-80X90 S_{DAP} TLD = > S_{DAP} pred PASS Woman Medium Standard quality FOV 110X80 S_{DAP} TLD > PASS Child medium

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						Standard quality FOV 80X80-80X90 SID Adult S_{DAP} TLD > S_{DAP} pred PASS
						Child medium Standard quality FOV 80X80-80X90 SID Child S_{DAP} TLD > S_{DAP} pred PASS
					Voxel Noise [a.u.] with TLD cassette including new PAN-CBCT sensor (VN_{TLD}) ≤ Voxel Noise [a.u.] predicate (VN)	Woman Medium Standard quality FOV 80X90-

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						VN_{TLD} < VN PASS
						Woman Medium Standard quality FOV 110X80 VN_{TLD} < VN PASS
						Child medium Standard d quality FOV 80X80-80X90 SID Adult VN_{TLD} < VN PASS
						Child medium Standard d quality

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						FOV 80X80-80X90 SID Child VN_{TLD} < VN PASS
					NPS_{0D} [a.u.^{2}] with TLD cassette including new PAN-CBCT sensor ≤ NPS_{0D} [a.u.^{2}] pedicate	Woman Medium Standard quality FOV 80X90- $NPS_{0D\ TLD}$ < NPS_{0D} PASS
						Woman Medium Standard quality FOV 110X80 $NPS_{0D\ TLD}$ < NPS_{0D} PASS
						Child medium

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						Standard quality FOV 80X80-80X90 SID Adult $NPS_{0D\ TLD} < NPS_{0D}$ PASS
						Child medium Standard quality FOV 80X80-80X90 SID child $NPS_{0D\ TLD} < NPS_{0D}$ PASS
				IEC 60601-2-63 203.8.5.3 Correspondence	c) along each of the two axes of the IMAGE RECEPTION AREA, the	SID Adult edge ≤ 20mm PASS

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
				between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA (rectangular area)	edges of the X-RAY FIELD shall not exceed the corresponding edges of the EFFECTIVE IMAGE RECEPTION AREA by more than 2 cm or 3 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE RECEPTION PLANE is normal to the X-RAY BEAM AXIS, whichever the larger;	Sid Child edge ≤ 20mm PASS
					d) the sum of the discrepancies on both axes shall not exceed 3 cm or 4 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE, whichever the larger	< 30mm PASS

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
					e) along the axis of the IMAGE RECEPTION AREA that is parallel to the direction of the scanning, the X-RAY FIELD shall not exceed the EFFECTIVE IMAGE RECEPTION more than 1 mm on each side.	≤ 1 PASS
					f) along the axis of the IMAGE RECEPTION AREA that is perpendicular to the direction of the scanning the X-RAY FIELD shall not exceed the EFFECTIVE IMAGE RECEPTION AREA	=0 PASS
				21 CFR 1020.31 f) 4)	field does not exceed each dimension of the image receptor by more than 2 percent of the SID,	<u>PAN</u> ≤ 2% PASS
						<u>PAN reduced SID</u> ≤ 2% PASS
						<u>CBCT</u> ≤ 2% PASS

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						CBCT reduced SID ≤2% PASS
					align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID,	Only for PAN and CEPH PASS
		Addition of FOV	No variation in intended use	N.A.	N..A.	N.A.
4	Addition of TLD cassette	New TLD cassette	Mechanical **3D**. Cutting or severing, trapping, crushing, impact, instability. 2) Fall of suspended and moving masses	ES60601-1: 2005/(R)2012 and A1:2012,	Safety factor ≥2.5	k >>2.5 respect to local collapse PASS
		New Child special exam	**29A** Unintended use of the device due to	IEC 60601-1-6	The criteria to pass usability verification are that all the comments are positive.	PASS

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
			human factors Event 6) Misplace adult patients during child exam Inadequate arrangement of controls and indicators			
		New tool Child special exam	**4C**. Contact allergy due to Inappropriate materials, not biocompatible	Same material, same plastic injection process of chin rest, bite block ISO 10993-5: 2009 ISO 10993-10: 2010	Cytotoxicity: No cytotoxic Hypersensitivity: Not sensitizing –	PASS PASS
		True Low dose (TLD) (reduction of SID)	**21A.** Ionising radiation hazard Harm: biological effects due to X-ray	Bench test PAN mode according to same protocol used in X-MIND trium Submission	Absence of artifacts	Both verified PASS
					Equal Hight contrast resolution	Both 3.1 lp/mm

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
			ionising radiation due to event 4) Unwanted x-ray exposure due to poor image quality (inadequate for diagnostic purpose)	K160166		PASS
					Equal Low contrast resolution	Both 4 holes visible PASS
					Declared DAP PAN CHILD NEDIUM SID ≤predicate	38.77<52.7 PASS
				Bench test CBCT mode according to same protocol used in X-MIND trium Submission K160166	Same or superior trade-off between dose and image quality (i.e. System Indicator (SI) in CBCT) $S_{DAP} \geq S_{DAP\ predicate}$ $S_{DAP}=\frac{CNR}{DAP\left(\frac{1}{2\cdot V_{50\%}}\right)^2}$ CNR is the contrast to noise	Woman Medium Standard quality FOV 80X80-80X90 S_{DAP} TLD > S_{DAP} pred PASS

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
					ratio (overaged value from 5 measurements) DAP is the dose area product declared in IFU V50% is the resolution indicator at 50% modulation	Woman Medium Standard quality FOV 110X80 S_{DAP} TLD > S_{DAP} pred PASS
						Child medium Standard quality FOV 80X80-80X90 SID Adult S_{DAP} TLD => S_{DAP} pred PASS

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						Child medium Standard quality FOV 80X80-80X90 SID Child S_{DAP} TLD > S_{DAP} pred PASS
					Voxel Noise [a.u.] with TLD cassette including new PAN-CBCT sensor (VN_{TLD}) ≤ Voxel Noise [a.u.] predicate (VN)	Woman Medium Standard quality FOV 80X90- VN_{TLD} < VN PASS
						Woman Medium Standard quality FOV 110X80 110X90

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						VN_{TLD} < VN PASS
						Child medium Standard d quality FOV 80X80-80X90 SID Adult VN_{TLD} < VN PASS
						Child medium Standard d quality FOV 80X80-80X90 SID Child VN_{TLD} < VN PASS
						Woman Medium

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
					NPS_{0D} [a.u.^{2}] with TLD cassette including new PAN-CBCT sensor ≤ NPS_{0D} [a.u.^{2}] predicate	Standard quality FOV 80X90 90X90- $NPS_{0D\ TLD}$ < NPS_{0D} PASS
						Woman Medium Standard quality FOV 110X80 110X90 $NPS_{0D\ TLD}$ < NPS_{0D} PASS
						Child medium Standard d quality FOV 80X80-80X90 SID Adult

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						$NPS_{0D\ TLD} < NPS_{0D}$ PASS
						Child medium Standard quality FOV 80X80-80X90 SID Child $NPS_{0D\ TLD} < NPS_{0D}$ PASS
			Detectability study	As requested by FDA RAI 23th August 2019	Same pathological or clinically relevant conditions identifiable both in the STD protocol scan and in the TLD protocol one	PASS All pathological or clinically relevant conditions identified with STD protocol scan have been identifies also with

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
						the LD protocol one Note Pos. 45 “worn out dental neck” not identified nor in standard mode nor in TLD configuration
		Software (new movement managed by firmware)	**PEMS 1.6** Unintended movement of the U-arm, patient support, SID regulation axis or mobile column /patient	Same protocol used protocol used in X-MIND trium Submission K160166	All test shall be PASS	All test PASS

Id	Device Change		Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
5	Change of beam limiting device	Change of aperture dimensions	**5A** Biological effects due to X-ray ionising radiation. 2) Unwanted X-ray due to unsuitable or fault shielding (causing leakage radiation), filtration or collimation	IEC 60601-2-63 203.8.5.3 Correspondence between X-RAY FIELD and EFFECTIVE IMAGE RECEPTION AREA (rectangular area)	c) along each of the two axes of the IMAGE RECEPTION AREA, the edges of the X-RAY FIELD shall not exceed the corresponding edges of the EFFECTIVE IMAGE RECEPTION AREA by more than 2 cm or 3 % of the indicated FOCAL SPOT TO IMAGE RECEPTOR DISTANCE when the IMAGE RECEPTION PLANE is normal to the X-RAY BEAM AXIS, whichever the larger;	<u>SID Adult</u> edge < 20mm PASS
						<u>Sid Child</u> edge < 20mm PASS
				21 CFR 1020.31 f) 4)	field does not exceed each dimension of the image receptor by more than 2 percent of the SID,	<u>PAN</u> < 2% PASS
						<u>PAN reduced SID</u> < 2% PASS

Id	Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
					<u>CBCT</u> < 2% PASS
					<u>CBCT reduced SID</u> < 2% PASS
				align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID,	PASS Only for PAN and CEPH
			21 CFR 1020.30 (k)	Same geometry as the previous version	PASS
6	Addition of self standing version self standing base	Hazardous situations: **3D**. Cutting or severing, trapping, crushing, impact, instability. Event (8) Unbalancing of the self-standing device due to base mechanical	IEC 60601-1 9.4.2 instability overbalance	At 10° in all directions no overbalance	PASS
			9.8.2 tensile safety factor	Safety factor ≥ 4	>4 with respect to yielding (local plastic strains) >4 with respect to local collapse

Id	Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
		failure or base-column connection mechanical failure.			PASS
7	The Low Dose functionality	X-ray: **AIS 5** **14** Biological effects due to X-ray ionising radiation Event 2: Overexposure of X-ray due to the need of exposure to be repeated due to fault in AIS software functions - New acquisition	Bench test according to same protocol used in X-MIND trium Submission K160166	Same or superior trade-off between dose and image quality (i.e. System Indicator (SI) in CBCT) S_{DAP} low dose≥ S_{DAP} standard protocol $S_{DAP}=\frac{CNR}{DAP\left(\frac{1}{2\cdot V_{50\%}}\right)^2}$ CNR (average on 5 measurements) DAP (declared in IFU)	<u>Man</u> S_{DAP} low dose > S_{DAP} standard protocol PASS <u>Woman</u> S_{DAP} low dose > S_{DAP} standard protocol PASS <u>Child</u> S_{DAP} low dose > S_{DAP} standard protocol PASS

Id	Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
				$\Delta\%_{VN} \leq 10\%$ $\Delta\%_{VN} = \frac{VNld - VNs}{100 * VNsd}$ $VNld =$ Voxel Noise [a.u.] low dose protocol $VNsd =$ Voxel Noise [a.u.] standard protocol	Man $\Delta_{VN}\% <$ 10% PASS
					Woman $\Delta_{VN}\% <$ 10% PASS
					Child $\Delta_{VN}\% <$ 10% PASS
				$\Delta\%_{NPS} \leq 30\%$ $\Delta\%_{NPS} = \frac{NPSld - NPSsd}{100 * NPSsd}$ $NPSld =$ NPS^{0D} [a.u.^{2}] low dose protocol $VPSsd =$ NPS^{0D} [a.u.^{2}] standard dose protocoll	Man Δ_{NPS}<30% PASS
					Woman Δ_{NPS}<30% PASS
					Child Δ_{NPS}<30% PASS

Id	Device Change	Risks	Verification/Validation Method(s)	Acceptance Criteria	Summary of results [3]
			Detectability study as requested by FDA RAI 23th August 2019	Same pathological or clinically relevant conditions identifiable both in the STD protocol scan and in the LD protocol one	PASS All pathological or clinically relevant conditions have been identified both in the STD protocol scan and in the LD protocol one

Table 9: change traceability matrix

Details on Risk Management file, verification and validation are available in section 16

XIV. PERFORMANCE, SAFETY, EMC TESTS

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on X-MIND trium.
The performance tests on X-MIND trium V2 have been conducted by a Nationally Recognized Testing Laboratory (NRTL) in order to verify:

- compliance with general requirements for basic safety and essential performance of medical electrical equipment, dental intra-oral X-ray equipment, diagnostic X-ray equipment, programmable electrical medical systems, high-voltage generators of diagnostic X-ray generators, X-ray source assemblies and X-ray tube assemblies for medical diagnosis;
- compliance with usability requirements;

- compliance with electromagnetic compatibility requirements.

The following table illustrates the standards to which X-MIND trium V2 complies, compared to those related to X-MIND trium

Proposed device	Predicate device
X-MIND trium	X-MIND trium
IEC 60601-1 3rd ed.	IEC 60601-1 3.1rd ed.
ANSI/AAMI ES60601-1: 2005	ES60601-1: 2005/(R)2012 and A1:2012
CAN/CSA C22.2 No. 60601-1:08	CAN/CSA C22.2 No. 60601-1:14
IEC 60601-1-2: 2007	IEC 60601-1-2: 2014
IEC 60601-1-3: 2008	IEC 60601-1-3: 2013
IEC 60601-2-63: 2012	IEC 60601-2-63: 2017
IEC 60601-1-6: 2010	IEC 60601-1-6: 2013
IEC 62366: 2007	IEC 62366: 2016
ISO 14971[4]	ISO 14971

Table 10: comparison between the standard applied

All the test reports for X-MIND trium are available in Section 16 of this submission.

X-MIND trium has been tested according to approved verification protocols to assure its conformity to the following parts of USA Code of Federal Regulations relating to PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS USA

21 CFR §1020.30 Diagnostic x-ray systems and their major components.

21 CFR §1020.31 Radiographic equipment.

21 CFR §1020.33 Computed tomography (CT) equipment.

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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 submissions for software contained in medical devices". The software for this device was considered a "moderate" level of concern, since a failure or latent flow could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Performance testing - Bench

Bench testing was used to evaluate the trade-off between the image quality and radiation dose of the images obtained with dose reduction due to addition of two main aspects:

- TLD cassette (when using special exam for child)
- Low Dose functionality, CBCT mode only

The technical bench tests issued to evaluate the performance and safety of the TLD (True Low Dose) cassette, reduced SIDs and the LD (Low Dose) functionality have been integrated by a clinical detectability analysis that provided evidence that the overall diagnostic quality of the CBCT datasets and dental panoramic images obtained by using the TLD or the LD functionality is basically the same as the images obtained in standard scan protocols.

The detectability analysis consisted in submitting the radiographs of cadavers to a set of intended users (radiologist, dentist, oral surgeon), who evaluated the visibility of anatomical structures and features of interests in the different scanning conditions.

Based on the bench test results on image quality and radiation dose and on the results of the detectability study obtained with X-MIND trium cleared device and X-MIND trium proposed device (with TLD cassette and separately with Low Dose functionality), we can assume that the clinical performance obtained with the above changes is equal or better than the ones of the predicate device; these results, confirmed the equivalence of X-MIND trium proposed device to X-MIND trium predicate device.

XV. FDA guidance documents

Here below is shown the list of FDA guidance documents that X-MIND trium conforms to or that we referred during the development

- FDA Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s August 2005

- FDA Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices September 2016
- FDA Guideline Use of International Standard ISO 10993-1,"Biological evaluation of medical devices Part 1: Evaluation and testing June 2016
- FDA Guideline Recomended Content and format of complete Test reports for NOn-ClinicalBench performance Testing in 510K submission April 2019.
- FDA Guidance for "Pediatric Information for X-ray Imaging Device Premarket Notifications" dated November 2017
- FDA Guidance for the content of premarket submissions for software contained in medical devices
- May 2005
- FDA Guidance Content of premarket submission for management of cybersecurity October, 2014

I. CONCLUSIONS

Based on a comparison of intended use, indications, constructions, construction materials, principal of operation, features, technical data and performances including diagnostic quality of the acquired images,

X-MIND trium including changes listed above is safe and effective to perform its intended use as well as substantially equivalent predicate device X-MIND trium (already cleared version)