



Food and Drug Administration
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de Götzen S.r.l.
% Mr. Olivier Balouka
Legal Representative
Via Roma, 45
Olgiate Olona, Varese 21057
ITALY

November 15, 2016

Re: K160166
Trade/Device Name: X-MIND trium
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS, MUH
Dated: October 14, 2016
Received: October 26, 2016

Dear Mr. Balouka:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. Behind the signature, there is a faint, large, stylized "FDA" logo in blue.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160166

Device Name

X-MIND trium

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, the X-MIND trium can be applied for the following medical applications:

- Generic dentistry
- Dental implantology
- Dental surgery
- Maxillo-facial surgery
- Cephalometric analysis
- Carpus radiology

The intended population can be whatever, including 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 qualified and authorized physicians, surgeons and dentists.

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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	X-MIND trium 510 (k) Summary	510 (k) submission Section 5	
Via Roma, 45 21057 Olgiate Olona (VA)		Ed. 3.0	Of October 3 rd , 2016

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
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Contact Person: Olivier Balouka – olivier.balouka@acteongroup.com
Dario Bandiera – dario.bandiera@acteongroup.com

Date: October 3rd, 2016

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

III. PREDICATE DEVICE

Legally marketed device to which equivalence is claimed is:

PREDICATE DEVICE	
Device name	Hyperion X9
Manufacturer	CEFLA S.C.
Device product code	OAS
Subsequent product code	MUH
Regulation number	892.1750
Regulation name	Computed tomography x-ray system
Clearance date	05/10/2013
510(k) number	K123381

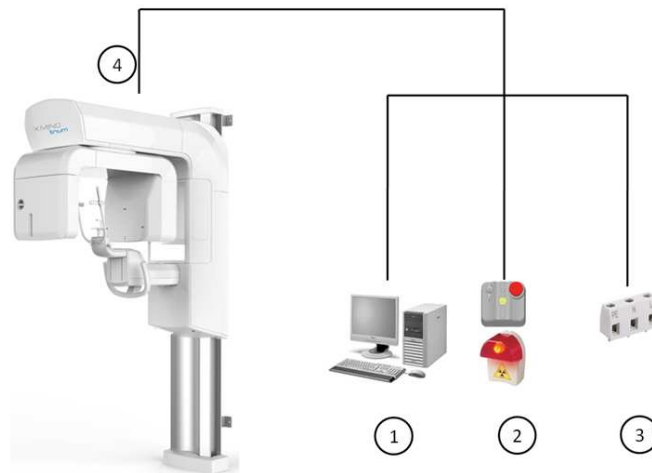
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This predicate has not been subjected to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

X-MIND trium is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, which consists of:



1. Operator's workstation

The operator's workstation is provided optionally for the PAN only unit.

The workstation allows the operator to perform the following procedures:

- Calibration of the medical device
- Acquisition parameters setting
- Radiological image acquisition
- Image visualization and post processing
- Periodic quality Tests

The workstation must have installed the following modules:

- ACTEON IMAGING SUITE (AIS) equipment management software + 2D diagnostic analysis
- AIS 3D app (CBCT)

Communication with the medical device occurs by means of Ethernet protocol.

2. X-MIND trium remote control and X-MIND trium light

X-MIND trium Remote Control

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

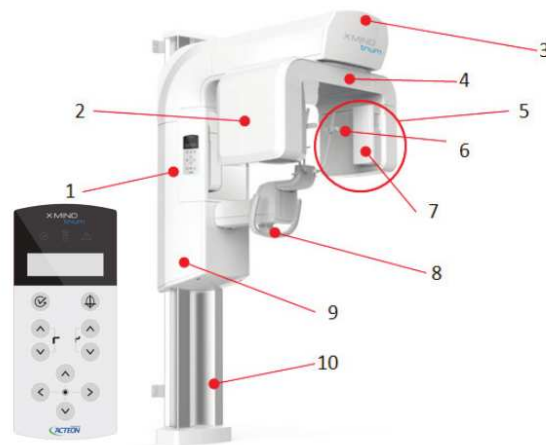
X-MIND trium Light



The X-MIND trium Light is an indicator light that warns that X-ray emission is in progress. It indicates no entry into the room when the red light is on; it also has a triangular danger sign that warns of X-ray hazards.

3. X-MIND Trium medical device

Overview of the medical device: **PAN/CBCT model:**



The X-MIND trium medical device for PAN/CBCT models consists of the following parts:

1. Control panel. The control panel provides an intuitive overview of the system to move the mobile column, move the bite block holder (only PAN/CBCT version), move the U-arm, turn the positioning lasers on and off and activate the X-MIND trium medical device.

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2. X-ray generator. The X-ray assembly is the source of the X-ray beam. An automatic collimator shapes the X-Ray beam, whereas the electronic control ensures stability and accuracy of the selected loading factors (exposure time, kVp and anodic current). A filter is used to harden the beam and remove low-energy ionizing radiations, thereby obtaining suitable radiation quality whilst reducing the dose absorbed by the patient; the filter's material is aluminium for PAN and CEPH exams, aluminium + copper for CBCT exams.
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 PAN/CBCT Detector sliding group and the X-ray generator. This is the rotating and translating part of the medical device, which moves around the patient during the image acquisition phase; it can as well be moved in two horizontal directions (X and Y) by the operator during the setup of the exam, in order to obtain the best superimposition between the patient's head anatomy and the diameter of the Field of View (FOV).
5. Detector sliding group. It contains detectors that acquire PAN and CBCT images.
6. CBCT detector. Dedicated detector for CBCT acquisition.
7. PAN detector. Dedicated detector for PAN acquisition.
8. Patient support. The patient support allows stabilising and immobilising the patient. It can be moved vertically in order to obtain the best superimposition between the patient's head anatomy and the height of 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 the F Group.

Overview of the medical device: **Cephalometric extension:**

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The Cephalometric version of X-MIND trium medical device consists of the parts listed above and of the following additional parts:

11. CEPH arm extension. Can be positioned both on the right or left side of the vertical column.
12. CEPH control panel. Provides an intuitive overview of the system to move the mobile column and activate the X-MIND trium medical device.
13. CEPH patient support. Allows stabilising and immobilising the patient during CEPH exams, by means of ears rest and nasion rest.
14. CEPH detector sliding group. Enables to slide the detector to follow the X-Ray beam.
15. CEPH secondary collimator is positioned on the U-arm; it translates during X-Rays (keeping aligned the X-Ray beam emerging from the tube head with the CEPH detector);
16. CEPH detector. Gives 2D image of the whole patient head; this detector can optionally be moved from his position on CEPH arm to the PAN position on the U-arm.

The whole equipment is manufactured according to the international regulations in force relevant to ionizing radiation protection as well as mechanical and electrical safety concerning electro medical devices.

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Control panels

Equipment control panels are used during patient positioning phase.

Proper keys allow to move equipment to the initial position before patient access, turn on the positioning lasers, adjust the U-arm position to align the patient to X-ray beam and set the "ready to X-ray" status.

Some keys are duplicated on the CEPH control panel, for use during patient positioning for CEPH exams.



Equipment control panel



CEPH control panel

X-MIND trium remote control

The X-MIND trium remote control must be kept in a safe place protected against radiations, in compliance with local standards in force concerning radiation protection. The X-MIND trium remote control allows the operator to activate or deactivate X-ray emissions from the control room.

The components are listed below with a brief description of the parts.

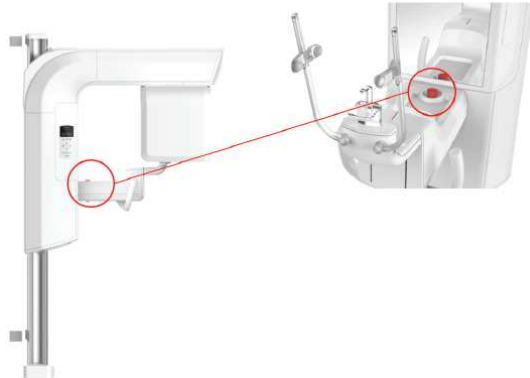
1. Safety key selector switch. Deactivates the X-ray emission switch to prevent accidental exposure.
2. X-ray emission LED. Remains on during the entire acquisition.
3. Remote emergency switch. Allows stopping the device in the event of emergency.
4. X-ray emission switch. Activates acquisition.

Emergency switches

This device is equipped with two emergency switches that allow to stop the movement of parts and X-ray emission in the event of an emergency.

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Patient emergency switch



The patient emergency switch is installed on the head support and is within the patient's reach, to allow both the patient and the operator to stop the device in the event of panic or hazards, sudden column motion or any anomaly. The operator must inform and instruct the patient on the emergency procedures and on the use of the emergency switches of the device, as indicated in this chapter.

Remote emergency switch



1= Remote emergency switch

The Remote emergency switch is located on the X-MIND trium remote control. In case of an emergency, stop any movement of the device and X-ray emission by pressing either the patient emergency switch or the remote emergency switch. This action puts the device in the emergency status. To reset the emergency status, first solve the emergency condition and then release the emergency switch by turning it clockwise until it reaches its initial position.

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X-ray exposure switch



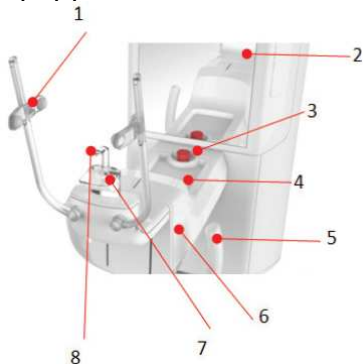
X-ray exposure switch

To activate the exposure, the operator must press and hold the X-ray exposure switch for the entire acquisition. Meanwhile, the yellow X-ray exposure LED stays on to indicate the X-ray emission.

If the operator removes his/her finger from the exposure button before the acquisition is complete, the X-ray emission and U-arm rotation will be interrupted and the X-ray exposure LED will turn off. At this point, an error message appears in the AIS software. This message must be closed before using the medical device again.

Head support for PAN/CBCT exams

The head support positions and immobilizes the patient before the scan. It is equipped with a chin rest and forehead support to ensure maximum stability.

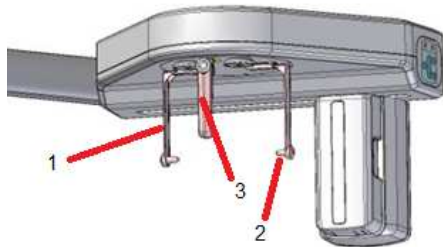


1. Temple rest
2. Patient mirror
3. Local emergency switch
4. Courtesy tray
5. Handlebar
6. Temple knob
7. Chin rest
8. Bite block

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Head support for CEPH exams

The head support in CEPH arm positions and immobilizes the patient before the scan. It is equipped with a couple of ear rests and a nose support to ensure maximum stability.



1. Ear rest
2. Ear rest knob
3. Nose support

To adapt to the patient's anatomy, the CEPH head support is equipped with:

- Ear rest knob for horizontal ear rest movement
- Nose support that can be manually moved in horizontal and in vertical.

Accessories

Temple rest

The temple rest supports provide support, frontal and lateral stability to the patient's head for all types of examination.



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Chin rest



The chin rest allow immobilizing the patient's mouth during the 3D CBCT and the 2D maxillary sinus exams; it should also be used for 2D panoramic exams in case of edentulous patients.

Sliding bite block and chin rest assembly



The combined use of the bite block and the chin rest improves the stability of the jaws, allows separating the teeth during the acquisition and places in the same vertical plane the superior and the inferior incisors.

The bite block and chin rest assembly must be used for immobilizing the patient in panoramic exams except in case of edentulous patients; in addition, it can be used in CBCT scans when an improved 3D reconstruction of the dental crown surface is required.

TMJ nose support

This support must be used for TMJ examinations since it is specifically designed to stabilize the patient's head in both open mouth and closed mouth conditions.

Calibration tray and geometric calibration phantom

The Calibration tray is used to position the geometric calibration phantom during the calibration procedure of the CBCT apparatus.

The calibration procedure consists of a scan of the calibration phantom and the estimation of a set of parameters that describe the configuration of the system.

Quality phantom support for Germany

This accessory is intended to position the QUART DVT test phantoms for QA/QC of CBCT functionality for X-MIND trium installed in Germany.

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X-MIND trium configurations

X-MIND trium can be sold in these configurations:

PAN only

- The equipment can carry out uniquely exams of the PAN group (PAN, TMJ, Sinus).
- The image detector is fixed to the PAN bay.
- All the exams are carried out with the same extension in height (146 mm height on image receptor), since the collimator has fixed dimensions.
- The equipment can be upgraded in a later stage by replacing and adding several parts.

PAN and CBCT

- The equipment can carry out both 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.
- 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 as specified in the technical data appendix.
- The equipment can be upgraded in the field to CEPH configuration by simple procedure, adding CEPH arm with CEPH image detector and replacing the existing PAN image detector.

PAN / CEPH

- The equipment can carry out both exams of the PAN group (PAN, TMJ, Sinus) and of the CEPH group (AP/PA, LL, carpus).
- The image detector can optionally be unique, for both PAN and CEPH exams; in this case it must be manually moved by the operator from PAN bay to CEPH bay and vice versa, depending on the selected exam. Otherwise, two different dedicated detectors can be provided: one for CEPH exams and the other one for PAN exams.
- The 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.

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- The equipment can be upgraded in-field to CBCT configuration by a simple procedure, adding the CBCT image detector and the bite block holder with vertical movement.

PAN / CBCT / CEPH

- The equipment can carry out all feasible exams of the PAN group (PAN, TMJ, Sinus), CEPH group (AP/PA, LL, carpus) and CBCT group.
- There are optionally two image detectors, one for PAN/CEPH and one for CBCT exams; in this case the PAN/CEPH image detector must be manually moved by the operator from PAN bay to CEPH bay and vice versa; otherwise three image detectors, one for PAN, one for CEPH and one for CBCT exams.
- To carry out PAN or CEPH or CBCT exams 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;
- CBCT exams can be carried out at different FOV dimensions as specified in the technical data appendix.

Exams

In its different configurations, X-MIND trium equipment carries out the following exams:

Panoramic group

The panoramic group includes all the 2D radiographs of the jaws, dentition, temporomandibular joints and maxillary sinuses.

- 1) Standard panoramic
 - Full scan
 - Right side only
 - Left side only
- 2) Sectorial panoramic with improved orthogonality
 - Full scan
 - Right side only
 - Left side only
- 3) Frontal panoramic
- 4) Bitewings

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- 5) Frontal temporomandibular joint with closed or open mouth
 - Both sides
 - Left TMJ only
 - Right TMJ only
- 6) Lateral temporomandibular joint with closed or open mouth
 - Both sides
 - Left TMJ only
 - Right TMJ only
- 7) Frontal maxillary sinuses
- 8) Lateral maxillary sinuses
 - Left sinus only
 - Right sinus only

CBCT group

The CBCT group includes all the 3D CBCT examinations of the dental and maxillofacial regions.

Here below the size of the reconstructed volumes expressed as diameter x height.

- 1) Dental FOV
 - 40mm x 40mm
 - 60mm x 60mm
 - 80mm x 80mm
 - 110mm x 80mm
- 2) ENT FOV – Nose
 - 110mm x 80mm
- 3) ENT FOV – Ear
 - Left ear only, 60mm x 60mm
 - Right ear only, 60mm x 60mm

Cephalometric group

- 1) Frontal (AP/PA)
- 2) Lateral (LL)
- 3) Hand acquisition (Carpus - special support needed)

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V. INDICATIONS 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;
- 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.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	Proposed	Predicate
	X-MIND trium	HYPERION X9
Manufacturer	de Götzen S.r.l. – Acteon Group Via Roma, 45 21057 Olgiate Olona VA - Italia	Cefla s.c. Via Selice Prov.le, 23/a 40026 Imola BO - Italia
510 (k) number	K160166	K123381
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; - 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.	Hyperion X9 is a digital panoramic, cephalometric and tomographic extra-oral X-ray system, indicated for use in: - Producing panoramic X-ray images of the maxillo-facial area, for diagnostic examination of dentition (teeth), jaws and oral structures; - Producing radiographs of jaws, parts of the skull and carpus for the purpose of cephalometric examination with tele-radiographic arm (CEPH); - Producing tomographic images of the oral and maxillofacial structure, for diagnostic examination of dentition (teeth), jaws, oral structures and some cranial bones if equipped with CBCT option.

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Characteristic	Proposed	Predicate												
	X-MIND trium	HYPERION X9												
	From a clinical point of view, X-MIND trium can be applied for the following medical indications: <table><tr><td>Generic dentistry</td></tr><tr><td>Dental implantology</td></tr><tr><td>Dental surgery</td></tr><tr><td>Maxillo-facial surgery</td></tr><tr><td>Cephalometric analysis</td></tr><tr><td>Carpus radiology</td></tr></table>	Generic dentistry	Dental implantology	Dental surgery	Maxillo-facial surgery	Cephalometric analysis	Carpus radiology	From a clinical point of view, X-MIND trium can be applied for the following medical indications: <table><tr><td>Generic dentistry <i>Conservative dentistry;</i> • <i>Endodontics;</i> • <i>Periodontology;</i> • <i>Dental prostheses;</i> <i>Orthodontics.</i></td></tr><tr><td>Dental implantology <i>Implantation</i></td></tr><tr><td>Dental surgery <i>Surgical dentistry</i></td></tr><tr><td>Maxillo-facial surgery <i>Maxillofacial surgery</i></td></tr><tr><td>Cephalometric analysis <i>Functional diagnostics and treatment of craniomandibular dysfunctions</i></td></tr><tr><td>Carpus radiology</td></tr></table>	Generic dentistry <i>Conservative dentistry;</i> • <i>Endodontics;</i> • <i>Periodontology;</i> • <i>Dental prostheses;</i> <i>Orthodontics.</i>	Dental implantology <i>Implantation</i>	Dental surgery <i>Surgical dentistry</i>	Maxillo-facial surgery <i>Maxillofacial surgery</i>	Cephalometric analysis <i>Functional diagnostics and treatment of craniomandibular dysfunctions</i>	Carpus radiology
	Generic dentistry													
	Dental implantology													
	Dental surgery													
	Maxillo-facial surgery													
	Cephalometric analysis													
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	Generic dentistry <i>Conservative dentistry;</i> • <i>Endodontics;</i> • <i>Periodontology;</i> • <i>Dental prostheses;</i> <i>Orthodontics.</i>													
Dental implantology <i>Implantation</i>														
Dental surgery <i>Surgical dentistry</i>														
Maxillo-facial surgery <i>Maxillofacial surgery</i>														
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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.	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	1) PAN - standard panoramic - child panoramic - TMJ												

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Characteristic	Proposed	Predicate
	X-MIND trium	HYPERION X9
	- 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	- bitewing - sectorial panoramic - maxillary sinuses 2) CEPH: - frontal (AP/PA) - lateral (LL) - carpus (with special hand support) 3) CBCT: - full view - extended view
Device power supply		
Type of power supply	Single-phase alternating current power supply	Single-phase alternating current power supply
Nominal voltage	100 V - 240V	115 V – 240 V
Maximum voltage variation	±10%	±10%
Nominal current	7 A (@ 240 V) 15 A (@ 100 V)	7 A (@ 240 V) 14 A (@ 115V)
Frequency	50 - 60 Hz	50 - 60 Hz
Operation mode	Continuous operation with intermittent X-ray loading	Continuous operation with intermittent X-ray loading
Electrical classification (IEC 60601-1)		
Protection against electrical shock	Class I	Class I
Degree of protection against electrical shock	Type B	Type B
EMC classification		
Emission	Group 1, Class A	Group 1, Class B

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Characteristic	Proposed	Predicate
	X-MIND trium	HYPERION X9
X-RAY source assembly		
Manufacturer of the X-ray tube	CEI	CEI
X-ray tube model	OPX/105	OPX/105
Nominal High Voltage	60 - 85 kV for PAN/CEPH 80 - 90 kV for CBCT	60 - 85 kV for PAN/CEPH 80 - 90 kV for CBCT
Anode heat storage capacity	30 kJ	30 kJ
Nominal focal spot diameter	0.5 mm	0.5 mm
Anode material	Tungsten	Tungsten
Target Angle	5°	5°
Anodic current	4 - 10 mA for PAN/CEPH 4 - 12 mA for CBCT	4 - 10 mA
Total filtration	2.8 mm Al for PAN/CEPH at 85 kV 7.0 mm Al for CBCT at 90 kV	3.2 mm Al for 2D mode at 85 kV 6.2 mm Al for 3D mode at 85 kV
HVL	3.4 mm Al for PAN/CEPH at 85 kV 5.2 mm Al for CBCT at 90 kV	3.6 mm Al for PAN/CEPH at 85 kV 5.0 mm Al for CBCT at 90 kV
Accuracy of the load parameters		
High Voltage	kV ± 10%	kV ± 10%
Current in the tube	mA ± 20%	mA ± 20%
Exposure time seconds	Seconds ± (10% + 1ms)	Seconds ± (10% + 1ms)
PAN/CEPH detector		
Detector technology	CMOS	CCD
Detector manufacturer	Hamamatsu	
Detector model	PAN: C10500D-42 CEPH: C10502D-42	
Pixel size	100 µm	48 µm (in PAN and CEPH exams the

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Characteristic	Proposed	Predicate
	X-MIND trium	HYPERION X9
		used pixel size is 96 µm, in accordance with the image size in pixel reported below)
Image size	PAN: 1480 px x 2658 px CEPH: 2232 px x 2673 px	PAN: 1528 px x 2797 px CEPH: 2291 px x 3125 px
Active area	PAN: 148 mm x 6 mm CEPH: 220 mm x 6 mm	PAN: 146 mm x 6 mm CEPH: 220 mm x 6 mm
Theoretical detector	4.5 lp/mm	10.4 lp/mm (@48 µm pixel size)
Actual in imaging ¹	4.5 lp/mm	5-7 lp/mm (@96 µm pixel size)
Detector resolution ² :	PAN: high contrast resolution: 3.1 lp/mm PAN: low contrast resolution: similar performance CEPH: high contrast resolution: 3.1 lp/mm CEPH: low contrast resolution similar performance	PAN: high contrast resolution: 2.8 lp/mm PAN: low contrast resolution: similar performance CEPH: high contrast resolution: 3.1 lp/mm CEPH: low contrast resolution similar performance
X-ray exposure time	PAN: 13.5 s CEPH: 18 s	PAN: 7.5 s – 13 s CEPH: 3.4 s
CBCT detector		
Detector technology	Flat panel CMOS	Flat panel CMOS
Detector manufacturer	Hamamatsu	
Detector model	C12280D-40	
Image voxel size	75 µm (minimum slice thickness)	75 µm (minimum slice thickness)
FOV (diameter x height)	40 mm x 60 mm 60 mm x 60 mm	50 mm x 50 mm 80 mm x 50 mm

¹ The dimension in pixel of the hyperion PAN image (1528px X 2797px) clearly indicates that hyperion is using only the lower resolution (Actual in imaging 96µm pixel), being the standard size of a panoramic around 150mm X 280mm

² Resolution data are taken from results of bench test performed on both devices.

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Characteristic	Proposed	Predicate
	X-MIND trium	HYPERION X9
	80 mm x 80 mm 110 mm x 80 mm	80 mm x 80 mm 110 mm x 50 mm 110 mm x 80 mm 110 mm x 130 mm
Detector resolution ² :	High contrast resolution: V10%: 1.61 lp/mm: High contrast resolution: V50%: 0.66 lp/mm	High contrast resolution V10%: 1.27 lp/mm High contrast resolution: V50%: 0.69 lp/mm
Rotation	360°	360°
Scanning time	12 s to 30 s maximum	18 s to 36 s maximum
X-ray real exposure time	6s (Normal quality) 7.2s (Medium quality) 9s (High quality)	3.6 s (High resolution) 9.0 s (Peak resolution)
Device mechanical data		
Dimensions	Footprint: PAN/CBCT: max 1100 mm x 1500 mm With CEPH: max 1720 mm x 1500 mm Height: 2350 mm	Footprint: max 1830 mm x 1520 mm Height: 2400 mm
Weight	PAN: 170 kg PAN/CBCT: 185 kg PAN/CBCT With CEPH: 215 kg	PAN/CBCT: 170 kg With CEPH: 190 kg
Mechanical configuration	Wall mount	Wall or floor support, free standing base available.
Patient position	Standing, seated or on wheel-chair	Standing, seated or on wheel-chair
Applicable Standards		
	IEC 60601-1 3 rd ed.	IEC 60601-1 3 rd ed.
	ANSI/AAMI ES60601-1: 2005	
	CAN/CSA C22.2 No. 60601-1:08	
	IEC 60601-1-2: 2007	IEC 60601-1-2: 2007
	IEC 60601-1-3: 2008	IEC 60601-1-3: 2008
	IEC 60601-2-63: 2012	IEC 60601-2-63: 2012
	IEC 60601-1-6: 2010	IEC 60601-1-6: 2010

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Characteristic	Proposed		Predicate	
	X-MIND trium		HYPERION X9	
	IEC 62366: 2007		IEC 62366: 2007	
	ISO 14971 ³			

Table 1 – Comparison between proposed and predicate devices.

Both X-MIND trium and Hyperion X9 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)

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.

In like manner, the predicated device Hyperion X9 comes with the software NNT allowing the operator to perform scans, execute primary/volumetric/secondary 3D image reconstructions, view the 3D dataset and create diagnostic structured report.

X-MIND trium software is described in detail in Section 16.2 of this submission. The following summary table shows a comparison of the functionalities for image processing, enhancing and visualization implemented in:

- 1) the 2D diagnostic analysis + AIS 3DApp
- 2) NNT

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

Software characteristic	X-MIND trium 2D analysis + AIS 3D app	Hyperion X9 NNT
Supported Image format	DICOM, JPEG, BMP, TIFF, GIF, PNG, DGI (proprietary format)	DICOM, JPEG, BMP

³ Compliance to this Standard was evaluated with reference to IEC 60601-1 3rd edition.

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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 sort + Rotation
Measuring function	+ Measuring distances + Measuring angles + Adding annotation + Viewing Pixel profile	+ Measuring distances + Measuring angles + Adding annotation + Viewing Pixel profile + Add marker + Add lines
Visualization filters	+ Gamma filter + Sharp filter + Equalize filter + Emboss filter + Reverse filter	+ Gamma filter + Sharp filter + Reverse filter + BEnh (bone enhancer) + STS (smooth soft tis.)
Pseudocolour analysis LUTs	+ Gray + Inverse Spectrum	+ Gray + Spectrum + Sepia + Blue + Film + Red + Flame
Windowing	+ Contrast-brightness set + Lower-Upper level + SHS optimal windowing	+ Contrast-brightness set + Lower-Upper level
Reporting	Included	Included
Functionalities and features for CBCT 3D dataset		
Basic image visualization features	+ Zoom and pan + Rotation + Flipping / mirroring, vertical / horizontal	+ Zoom and sort + Rotation
Measuring function	+ Measuring distances + Measuring angles	+ Measuring distances + Measuring angles

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	+ Adding annotation + Viewing Voxel profile + Measuring polygon + Measuring volumes + Measuring distance on 3D	+ Adding annotation + Viewing Voxel profile + Add marker + Add lines + Measuring distance on 3D
Processing filters	+ Sharp filter + Median filter + SHARP filter: denoiser and edge enhancer + STAR filter: streak and metal artifacts reduction	+ Gamma filter + Sharp filter + Reverse filter + BEnh (bone enhancer) + STS (smooth soft tis.)
Multi Planar Reconstruction (MPR)	+ Axial plane + Coronal plane + Sagittal plane	+ Axial plane + Coronal plane + Sagittal plane
Oblique MPR	Included	Included
Single and multiple cross sections visualization	Included + Setting number of sections + Setting distance of sections	Included + Setting number of sections + Setting distance of sections
Windowing	+ Contrast-brightness set + Lower-Upper level + Editing preset	+ Contrast-brightness set + Lower-Upper level
Display mode	+ MPR (voxel intensity) + Ray Sum + Maximum intensity projection (MIP) + Minimum intensity projection (minMIP) + SCOUT + Volume thickness selection (for MIP and Ray Sum)	+ MPR (voxel intensity) + Ray Cast + Maximum intensity projection (MIP) + Volume thickness selection (for MIP and Ray Cast)
3D volume rendering	+ Preset template + Editing of user-defined template	+ Preset template + Editing of user-defined template

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Surface Rendering	+ Surface generation + STL export	+ Surface generation
Curve Planar Reformation (CPR) for dental analysis	+ Dentascan wizard	+ Panorex synthesis
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	+ Crop function: 3D cut by orthogonal planes
Advanced 3D functions	+ Implant planning wizard + Nerve tracing + Importing 3D STL object in patient volume + STL implant library + Measuring bone density at implant sites + Bone/tissue removal	
General purpose functionalities		
Screenshot capture function	Image capture (AIS 3D app) 2D analysis module (Export)	Screenshot command

Table 2: comparison between Acteon Imaging Suite and predicate device software.

The above tables show that the two devices have the same intended use and equivalent performance specifications: they are both used to perform panoramic, cephalometric and CBCT analysis and they can be used to perform the same exams.

Both the proposed and the predicate device have the same type of power supply, similar nominal voltage (open range interval) and similar nominal current.

From the electrical classification point of view (IEC 60601-1) they are Class I type B, while the EMC classification (CISPR11) underlines a minor difference: Hyperion X9 is Group 1 – Class B (devices for usage in domestic establishments that are directly connected to a low voltage power supply network, which supplies domestic environment); X-MIND trium is Group 1 – Class A (devices for usage in all establishments other than domestic and that are not directly connected to a low voltage power supply network, which supplies domestic environment). For the intended use defined for X-MIND trium, this device has to be used only in clinics and dental surgeries or hospitals, not in domestic establishments. Therefore, the classification of the proposed device is equivalent to that of the predicate device.

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X-MIND trium and Hyperion X9 use the same X-ray tube to generate the radiation. The values of total filtration are not significantly different and they both comply with the requirements of the reference Standard (IEC 60601-1-3).

Mechanical characteristics of the proposed and predicate device are completely comparable.

General Tools and means made available by both software are equivalent.

From the comparison it is clear that the two devices have one significant difference: the technology of the panels used for panoramic and cephalometric exams. In fact, X-MIND trium uses the CMOS technology, while the predicate device Hyperion X9 uses the CCD technology.

For CBCT analysis, the two devices use the same type of detector (CMOS).

In order to verify the full equivalence of devices, we provided performance testing data as outlined in the FDA guidance document, "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices," and also 3D imaging performance (Homogeneity, Contrast to Noise Ratio (CNR), High contrast resolution (MTF), Nyquist frequency, Artifacts, Voxel Noise, Noise Power Spectrum (NPS)) compared with radiation dose data.

VII. 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 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.

Table of applicable standards available in "Table 1 – Comparison between proposed and predicate devices". illustrates the standards to which X-MIND trium complies, compared to those related to Hyperion X9.

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Both the devices comply with the same standards, but X-MIND trium is also compliant with IEC 60601-1 deviations for US and Canada.

For the proposed device X-MIND trium electrical, mechanical and environmental safety testing according to the standards IEC 60601-1: 2007, ANSI/AAMI ES60601-1: 2005, CAN/CSA C22.2 No. 60601-1:08, IEC 60601-1-3: 2008, IEC 60601-2-63: 2012, IEC 60601-1-6: 2010 and IEC 62366: 2007 were performed by Intertek Semko, which is a Nationally Recognized Testing Laboratory (NRTL). EMC testing was conducted in accordance with the standard IEC 60601-1-2: 2007 by Nemko S.p.A., which is a Nationally Recognized Testing Laboratory (NRTL) for the EMC tests (Accredia n. 1244).

The third parties assessed conformance of the medical device with the FDA-recognized standards and issued a final report for each of these standards.

All the test reports for X-MIND trium are available in Section 21 of this submission.

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.

Moreover General Tools and means made available by both software are equivalent.

Performance testing - Bench

The X-MIND trium is provided with three different flat panel detectors, each one intended for a specific mode of operation:

The bench tests were gathered according the mode of operation and the detector is use and they compared image quality and radiation dose according to the table below.

LIST OF BENCH TESTS		
Test group	Test	Endpoints / metrics
Cephalometric	Image quality test	- Image homogeneity - Artifacts - Low contrast spatial resolution - High contrast spatial resolution
	Radiation dose test	- Dose area product (DAP)
Panoramic	Image quality test	- Image homogeneity

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3D CBCT	Radiation dose test	- Artifacts - Low contrast spatial resolution - High contrast spatial resolution
		- Dose area product (DAP)
	Image quality test	- Homogeneity - Contrast to Noise Ratio (CNR) - High contrast resolution (MTF) - Nyquist frequency - Artifacts - Voxel Noise - Noise Power Spectrum (NPS)
		- Dose area product (DAP)

Table 3: list of bench tests

The conclusion of bench tests are the following:

X-MIND trium equipped with the C10502D-42 has been judged to provide cephalometric test pattern images of equivalent quality to those by the Hyperion X9.

The declared dose of both devices are under the DRL for Dental lateral cephalogram adult (32 mGycm²) according to NCRP REPORT No. 172 (2016). Therefore we can assume that technological difference in CEPH detectors does not raise different concerns on safety and effectiveness for X-MIND trium as compared to the predicate device.

X-MIND trium equipped with the C10500D-42 has been judged to provide cephalometric test pattern images of equivalent quality to those by the Hyperion X9.

The declared dose of both devices are under the DRL for Dental panoramic (100 mGycm²) according to NCRP REPORT No. 172 (2016). Therefore we can assume that technological difference in PAN detectors does not raise different concerns on safety and effectiveness for X-MIND trium as compared to the predicate device.

X-MIND trium equipped with the C12280D-40 used for CBCT scan has been judged to provide

for standard quality datasets a higher image quality with a slightly increased DAP for high quality protocols higher image quality performances with the same level of dose within the measurement uncertainty.

In order to support the claim of substantial equivalence we calculated a system index having as a reference standard DIN 6868-161

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$$S_{DAP} = \frac{CNR}{DAP \cdot \left(\frac{1}{2 \cdot V_{50\%}} \right)^2}$$

with the following results

Test group	Test type	Outcome
Cephalometric test group	Image quality	Substantial equivalence is confirmed by metrics
	Radiation dose	Both Hyperion and X-MIND trium are under the DRL suggested in the NCRP Report No. 172
Panoramic test group	Image quality	Substantial equivalence is confirmed by metrics
	Radiation dose	Both Hyperion and X-MIND trium are under the DRL suggested in the NCRP Report No. 172
CBCT test group: Standard quality protocols	Image quality	
	Homogeneity	Homogeneity for Hyperion is 2.8-10.9 times higher than X-MIND trium
	CNR	CNR for Trium is 2.12 ÷ 2.37 times higher than the CNR for Hyperion.
	MTF	the MTF plots show that Trium better maintains the high frequencies between 1.25 lp/mm and 1.5 lp/mm.
	Nyquist frequency	equivalent
	Absence of artifacts	equivalent
	Radiation dose	Hyperion is lower but the dose for X-MIND trium can be reduced by using other scan protocols
	System Indicator	Substantial equivalence is confirmed by S_{DAP}
CBCT test group: High quality protocols	Image quality	
	Noise	the voxel noise for Hyperion is 43.5% ÷ 53.8% higher than Trium.
	NPS	Noise content very similar at low frequencies, Hyperion shows a content of noise higher than trium at medium and high frequency
	Radiation dose	Substantial equivalence is confirmed by metrics

Furthermore, since the three detectors implemented in X-MIND trium haven't been cleared by FDA, the "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" has been followed, in order to provide performance testing data for all the three detectors. Data are contained in section 18 Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices and in section 18.3:X-MIND trium vs Hyperion X9 Clinical Considerations that constitutes an annex to previous section.

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VIII. CONCLUSIONS

Based on:

- comparison of parameters included in comparison table for devices and related softwares,
- results of bench test,
- results of application of Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices including comparison of clinical images obtained with X-MIND trium and predicate device;

we can state that X-MIND trium system is safe and effective to perform its intended use as well as substantially equivalent to the predicate device.