de Gotzen S.r.l.
% Dario Bandiera
Quality Assurance and Regulatory Affairs Manager
Via Roma, 45
Olgiate Olona, Varese 21057
ITALY

November 18, 2020

Re: K201382
Trade/Device Name: X-MIND prime 3D (under trademark Acteon)
I-MAX 3D (under trademark Owandy Radiology)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS, MUH
Dated: October 8, 2020
Received: October 13, 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)*
K201382

Device Name
X-MIND prime 3D (under trademark Acteon)
I-MAX 3D (under trademark Owandy Radiology)

Indications for Use *(Describe)*
X-MIND prime 3D (and I-MAX 3D under trademark Owandy Radiology) is an extra-oral dental panoramic and CBCT (aka CBVT) X-ray unit to take either two dimensional (panoramic, TMJ and sinus exams) or three dimensional radiographic exams of teeth, jaw and oral structures. The models with cephalometric arm will be able to take two dimensional cranial cephalometric exams in different projections and the wrist exam (Carpus) dedicated to the evaluation of the bone growth.
Two dimensional images are taken using the narrow beam technique. Three dimensional exams are taken using cone shaped X-ray beam technique; both of them are well known techniques.
The device is operated and used by dentists, radiologists and other legally qualified health care professionals, i.e. Prescription Use (Part 21 CFR 801 Subpart D).
The target patient population includes adults and pediatric patients from 7 years old [~27 kg (59.5 lb); 125 cm (49.2 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.

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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
Contact person:	Dario Bandiera – dario.bandiera@acteongroup.com
Date:	Septemberh 15th, 2020

Table 1: Submitter information

II. PROPOSED DEVICE

Name of the device:	X-MIND prime 3D (under trademark Acteon) I-MAX 3D (under trademark Owandy Radiology)
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

Table 2: Proposed device information

III. PREDICATE DEVICES

Legally marketed devices to which equivalence is claimed is:

PRIMARY PREDICATE DEVICE	
Device name	X-MIND prime 3D
Manufacturer	de Götzen S.r.l. – ACTEON Group
Device product code	OAS
Regulation number	892.1750
Regulation name	Computed tomography x-ray system
Clearance date	November 2nd, 2018
510(k) number	K180601

Table 3: Primary predicate device information

ADDITIONAL PREDICATE DEVICE	
Device name	DENTIOIII Series (DENTIOIII, DENTIOIII-S)
Manufacturer	HDX WILL CORP.
Device product code	MUH
Regulation number	872.1800
Regulation name	Extraoral source x-ray system
Clearance date	November 21st, 2018
510(k) number	K181297

Table 4: Additional predicate device information

IV. DEVICE DESCRIPTION

NOTE: In the following, all the reference to X-MIND prime 3D are applicable also to I-MAX 3D under trademark Owandy Radiology

X-MIND prime 3D is an X-ray device for the radiographic analysis of the maxillo-facial complex.
X-MIND prime 3D performs 2D Panoramic, Half-panoramic, Low dose Panoramic, Frontal dentition, Ortho Rad Panoramic, Bitewing Bilateral, Bitewing Left and Bitewing Right, 2D Sinus and 2D TMJ, 3D Dentition with multiple available FOV centered in different areas of the maxillo-facial complex (Full Dentition, Maxillary Jaw, Mandibular Jaw, Maxillary Teeth, Mandibular Teeth), 3D Sinus, 3D TMJ, AP and LL cephalometric exams, Carpus exam.

X-MIND prime 3D system can be used with the following type of patient:

- Patient population: the target patient population includes adults and pediatric patients from 7 years old [~25 kg (55 lb); 125 cm (49.2 in) standing height]. Anyway, the sustainability to X-ray exposure must be evaluated by surgeons, dentists and qualified and authorized physicians
- Patient status:
  - self-sufficient patient (the patient can autonomously place himself as requested by the physician)
  - non self-sufficient patient (the patient is assisted by medical personnel)
  - in any case the patient must be conscious, not anaesthetized and not incapacitated
- Nationality: multiple.

OVERVIEW OF THE DEVICE

The reason of the present submission is the introduction of a significative change on X-MIND prime 3D device (listing number D342123 and FDA clearance K180601).
This significant change mostly consists in the addition of the cephalometric arm to X-MIND prime 3D, as shown in overview figure below:

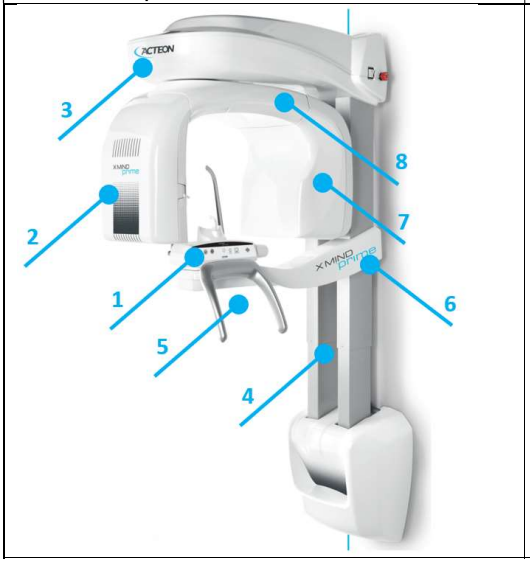
X-MIND prime 3D without CEPH arm	X-MIND prime 3D with CEPH arm
	

Figure 1: overview of the scanner in the configurations without and with the cephalometric arm

X-MIND prime 3D device consists of the following parts:

1	Control panel	The control panel provides an intuitive overview of the system and hold the keys to move up and down the column, turn on and off the positioning lasers and reset the device to the start exam position. 
2	Detector group	It contains the PAN/ CBCT detector for use in generating radiographic images of the maxillo-facial region. The same detector is used to acquire 2D panoramic and CBCT exams.
3	Fixed arm	It supports the rotating arm.
4	Telescopic Column	The telescopic column supports and moves the entire structure of the medical device. In the version without CEPH arm it is fixed to the wall without any footrest;

		in the version with CEPH arm it is fixed to the wall and resting on the floor.
5	Patient handgrip	Handgrips held by the patient during the exam.
6	Patient support	The patient support allows to stabilise and immobilise the patient. It is equipped with tools to position the patient head to fit the patient's anatomy to the Field of View (FOV).
7	X-ray generator	The X-ray assembly is the source of the X-ray beam during the exams. The beam is modelled by a collimator; the electronic control ensures precision and accuracy of selected loading factors (kVp and anodic current). The tubehead aluminium additional filtration fits the CFR 21 part 1020.30 and remove low-energy ionising radiations, obtaining suitable radiation quality while reducing the dose absorbed by the patient.
8	Rotating arm	The rotating arm supports detectors and X-ray generator. This is the rotating part of the medical device, which moves around the patient during the image acquisition phase of panoramic / 3D exams.
9	CEPH arm	In the version of X-MIND prime 3D with cephalometric arm, it allows the execution of cephalometric exams: radiographic images of the patient skull in LL and AP views and of the patient's wrist to evaluate the bone growth (using the carpus plate provided with the cephalometric function).
10	CEPH craniostat	The craniostat is the patient positioning aiming device (composed by ear and nasion rest) for the cephalometric exams.
11	CEPH 2^{ry} collimator	The CEPH 2^{ry} collimator is translating during X-Rays in sync with CEPH detector and 1^{ry} collimator (to collimate on CEPH detector the X-Ray beam emerging from the generator).
12	CEPH detector	The CEPH detector is translating during X-Rays in sync with CEPH 2^{ry} collimator and 1^{ry} collimator (to generate radiographic images of the patient skull in LL and AP views and of the patient's wrist.

Table 5: X-MIND prime 3D parts

EQUIPMENT CONFIGURATIONS

X-MIND prime 3D can be sold in these different configurations:

PAN / CBCT

In this configuration, X-MIND prime 3D is equipped only with the PAN/CBCT detector which allows to acquire both panoramic and CBCT exams.

PAN / CBCT / CEPH

The equipment can carry out the panoramic, 3D and cephalometric exams.
The device is equipped with a PAN/CBCT detector which allows to acquire both panoramic and CBCT exams.
On the cephalometric arm, a dedicated CEPH detector allows the acquisition of the cephalometric exams.

LIST OF EXAMS

X-MIND prime 3D is a complete panoramic X-ray system that can perform the following exams:

2D examination programs

- Standard Panoramic exam
- TMJ closed and open mouth: 4 slices are taken in the same image (left/right condyle, open/close mouth). Condyles are examined in lateral projection
- TMJ single phase
- Sinus P/A projection: one P/A projection, where both the maxillary sinuses are represented.
- Half Panoramic (left/right): panoramic acquired only on the right or left side of the mouth
- Ortho Rad Panoramic: panoramic projection limited to the dentition, obtained with X-ray beam constantly perpendicular to the arch. It allows to reduce superimposition of adjacent teeth and to improve visualization of possible interproximal caries
- Frontal Dentition: panoramic limited to the frontal dentition (canine to canine), that allows to improve the detail definition on incisors
- Low Dose Panoramic: panoramic with reduced angle of rotation to exclude the ascending ramus from the image. The result is a panoramic limited to the dentition area using a reduced patient dose
- Bitewing (Left/Right/Left and Right): the left or right projection allows the examination of lateral dentition (from eighth to fourth approximately), with optimized trajectory of rotating arm for a higher orthogonality of the x-ray beam on the adjacent teeth, to improve visualization of possible interproximal caries. Left and Right Bitewing projection performs both Bitewing views in sequence,

joining them on the same image

3D examination programs

- 3D Full Dentition (FOV 85 x 93 mm): 3D exam of the full dentition
- 3D Single Jaw (FOV 85 x 50 mm): 3D exam of a single dental arc with two different FOV positions: Maxillary, Mandibular
- 3D Mandibular Teeth (FOV 50 x 50 mm): 3D exam of a reduced part of the mandibular dentition, with five different FOV positions: Frontal, Premolars (right/left) and Molars (right/left)
- 3D Maxillary Teeth (FOV 50 x 50 mm): 3D exam of a reduced part of the maxillary dentition, with five different FOV positions: Frontal, Premolars (right/left) and Molars (right/left)
- 3D TMJ (FOV 85 x 93 mm): 3D exam of the temporomandibular joint with two different FOV positions (right/left)
- 3D Sinus (FOV 85 x 93 mm): 3D exam of the maxillary sinuses area

Cephalometric examination programs

- Cephalometric L-L projections (with formats 18x24, 24x24, 30x24 and 18x18, 24x18, 30x18): exam of the skull acquired in lateral projection. The selection between HS High Speed and HD High Definition is available.
- Cephalometric A-P projections (with formats 24x24 and 24x18): exam of the skull acquired in frontal position. The selection between HS High Speed and HD High Definition is available.
- Carpus Projection (with format 18x24): exam specifically intended for evaluating the state of calcification and the patient's bone growth trend. The exam is available only in HD High Definition mode.

For each exam it is possible to select patient type (Adult or Child) and the patient size (small, medium, large) to allow the automatic selection of the preset exposure parameters. Otherwise, the user has the possibility to select the exposure parameters manually, with a high voltage ranging between 60 and 86 kV in 2 kV steps, and with the anodic current ranging from 2 mA to 12.5 mA with R20 scale steps.

PRINCIPLES OF OPERATION

The X-ray generator and the detector (PAN/CBCT, CEPH) are the most important parts of the X-MIND prime 3D device and allow the acquisition of the radiographic images of the maxillofacial complex. The PAN/CBCT detector and the X-ray source are mounted on the rotating arm of the device, while the CEPH detector is mounted on the cephalometric arm.

During the panoramic and CBCT exams, the rotating arm rotates up to 200° (depending on the selected exams) around the patient's head, and the detector acquires a set of radiographic images. A collimator ensures an efficient use of the radiation, minimising the exposed area only on the anatomical region of interest.

The raw images are processed to obtain a 2D image (panoramic) or 3D reconstruction of the target volume.

In order to acquire the cephalometric exams, the CEPH detector performs a horizontal linear scanning of the skull, while the focus is kept in a fixed position, guaranteeing the same projection geometry as if using a film. The X-ray source is automatically aligned to digital sensor. The use of a secondary collimator on the cephalometric arm ensures the minimum level of radiation to the patient limiting the size of the fan shaped beam to the target region of interest. A digital filter is automatically applied to lateral cephalometric images to enhance the visibility of soft tissues profile while preserving the bone structures.

V. INDICATIONS FOR USE

X-MIND prime 3D (and I-MAX 3D under trademark Owandy Radiology) is an extra-oral dental panoramic and CBCT (aka CBVT) X-ray unit to take either two dimensional (panoramic, TMJ and sinus exams) or three dimensional radiographic exams of teeth, jaw and oral structures. The models with cephalometric arm will be able to take two dimensional cranial cephalometric exams in different projections and the wrist exam (Carpus) dedicated to the evaluation of the bone growth.

Two dimensional images are taken using the narrow beam technique. Three dimensional exams are taken using cone shaped X-ray beam technique; both of them are well known techniques.

The device is operated and used by dentists, radiologists and other legally qualified health care professionals, i.e. Prescription Use (Part 21 CFR 801 Subpart D).

The target patient population includes adults and pediatric patients from 7 years old [~27 kg (59.5 lb); 125 cm (49.2 in) standing height].

Anyway, the sustainability to X-ray exposure must be evaluated by surgeons, dentists and qualified and authorized physicians.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

NOTE: In the following, all the reference to X-MIND prime 3D are applicable also to I-MAX 3D under trademark Owandy Radiology

	Proposed device: X-MIND prime 3D	**Primary predicate device: Rotograph Prime 3D**	**Additional predicate device: DENTIOIII series (DENTIOIII, DENTIOIII-S)**
Intended Use	X-MIND prime 3D is an extra-oral dental panoramic and CBCT (aka CBVT) X-ray unit to take either two dimensional (panoramic, TMJ and sinus exams) or three dimensional radiographic exams of teeth, jaw and oral structures. The models with cephalometric arm will be able to take two dimensional cranial cephalometric exams in different projections and the wrist exam (Carpus) dedicated to the evaluation of the bone growth.	Rotograph Prime 3D is an extra-oral dental panoramic and CBCT (aka CBVT) X-ray unit to take either two dimensional (panoramic, TMJ and sinus exams) or three dimensional radiographic exams of teeth, jaw and oral structures.	The DENTIOIII series is intended for dental radiographic examination of the teeth and temporomandibular joints, specifically for panoramic and cephalometric examinations. It is to be used only by dental practitioners and/or radiologists

	Proposed device: X-MIND prime 3D	**Primary predicate device: Rotograph Prime 3D**	**Additional predicate device: DENTIOIII series (DENTIOIII, DENTIOIII-S)**
	Two dimensional images are taken using the narrow beam technique. Three dimensional exams are taken using cone shaped X-ray beam technique; both of them are well known techniques. The device is operated and used by dentists, radiologists and other legally qualified health care professionals, i.e. Prescription Use (Part 21 CFR 801 Subpart D). The target patient population includes adults and pediatric patients from 7 years old [~27 kg (59.5 lb); 125 cm (49.2 in) standing height]. Anyway, the sustainability to X-ray exposure must be evaluated by surgeons, dentists and qualified and authorized physicians.	Two dimensional images are taken using the narrow beam technique. Three dimensional exams are taken using cone shaped X-ray beam technique; both of them are well known techniques. The device is operated and used by dentists, radiologists and other legally qualified health care professionals. It can be used with both pediatric and adult patients.	

Table 6: Comparison of the intended use among proposed and predicate devices.

Detailed comparison of similarities and differences

The following table highlights the existing similarities for 2D and 3D exams between the proposed device and the primary predicate device.

	Proposed device: X-MIND prime 3D	**Primary predicate device: X-MIND prime 3D (Rotograph Prime 3D)**
2D Examination programs		
Panoramic exam	**Yes**	Yes
Ortho Rad Panoramic	**Yes**	Yes
Segmented Panoramic (Half panoramic, frontal dentition, bitewings)	**Yes**	Yes
Low dose panoramic	**Yes**	Yes
TMJ Closed/Open mouth	**Yes**	Yes
TMJ single phase	**Yes**	Yes
Sinus	**Yes**	Yes
2D Exam characteristics		
Magnification (Panoramic)	**1.28 constant**	1.28 constant
Source to image distance	**520 mm**	520 mm
Panoramic max image size	**equivalent to 15x30 cm film**	equivalent to 15x30 cm film
Adult panoramic scan time	**14 s**	14 s
Child panoramic exam with shorter scan time than adult panoramic exam	**12.8 s**	12.8 s

	Proposed device: X-MIND prime 3D	**Primary predicate device: X-MIND prime 3D (Rotograph Prime 3D)**
3D examination programs		
3D Full dentition	**Yes**	Yes
3D TMJ Left	**Yes**	Yes
3D TMJ Right	**Yes**	Yes
3D Sinus	**Yes**	Yes
3D Single Jaw (maxillary / mandibular)	**Yes**	Yes
3D teeth only (maxillary / mandibular)	**Yes**	Yes
3D High resolution mode	**Yes**	Yes
3D exam characteristics		
X-ray beam	**Cone Beam**	Cone Beam
Acquisition trajectory	**Single 200 degree rotation (except for 3D TMJ)** **Single 180 degree rotation (for 3D TMJ)**	Single 200 degree rotation (except for 3D TMJ) Single 180 degree rotation (for 3D TMJ)
Rotation time	**20 s (except for 3D TMJ)** **18 s (for 3D TMJ)**	20 s (except for 3D TMJ) 18 s (for 3D TMJ)
X-ray emission method	**Pulsed**	Pulsed
Reconstruction algorithm	**Feldkamp with the option of MAR (Metal Artifact Removal)**	Feldkamp with the option of MAR (Metal Artifact Removal)

	Proposed device: X-MIND prime 3D	**Primary predicate device: X-MIND prime 3D (Rotograph Prime 3D)**
Magnification	**1.37**	1.37
Source to image distance	**520 mm**	520 mm
X-ray emission time	**6.2 - 7 s**	6.2 – 7 s
Biggest FOV (Ø x H) mm (3D dentition, 3D TMJs, 3D sinus)	**85 mm x 93 mm**	85 mm x 93 mm
Size of acquired voxel (isotropic)	**175 µm**	175 µm
Size of acquired voxel in High resolution mode (isotropic), available on Other FOVs	**87.5 µm**	87.5 µm
2D/3D imaging detector		
Technology	**CMOS flat panel with Cesium Iodide (CsI) scintillator screen**	CMOS flat panel with Cesium Iodide (CsI) scintillator screen
Sensor active area (Height x Width)	**144 x 118.6 mm**	144 x 118.6 mm
Pixel size	**120 µm x 120 µm**	120 µm x 120 µm
Bit depth	**16 bit**	16 bit
Number of sensor pixels	**1200 x 988**	1200 x 988
Generator/tube characteristics		
X-ray generator	**High frequency**	High frequency
Focal spot value	**0.5 mm (IEC 60336)**	0.5 mm (IEC 60336)

	Proposed device: X-MIND prime 3D	**Primary predicate device: X-MIND prime 3D (Rotograph Prime 3D)**
Anode type	**Fixed**	Fixed
X-ray exposure time control	**Automatic – pre-programmed Microprocessor Controlled**	Automatic – pre-programmed Microprocessor Controlled
Independent kV-mA regulation	**Yes**	Yes
DAP Software	**Yes**	Yes
kV Range	**60 - 86 kV step 2kV**	60 - 86 kV step 2kV
Total filtration	**≥ 2.5 mm Al eq**	≥ 2.5 mm Al eq
mA range	**2 - 12.5 mA**	2 - 12.5 mA
Collimator	**Automatic**	Automatic
Patient positioning for panoramic and 3D exams		
Height adjustment	**Motorized**	Motorized
Positioning lights	**2 laser pointers**	2 laser pointers
Patient position	**Standing**	Standing
Patient positioning tools	**Temple clamps, bite block, chin support, head strip**	Temple clamps, bite block, chin support, head strip
Focal layer adjustment (prognatism compensation)	**Electronic, three positions, no patient movement**	Electronic, three positions, no patient movement
Patient positioning orientation vs the operator	**Face to face**	Face to face

	Proposed device: X-MIND prime 3D	**Primary predicate device: X-MIND prime 3D (Rotograph Prime 3D)**
Height of chin support from the floor	**978-1678 mm**	975-1635 mm
User interface		
Real time visualization	**Yes**	Yes
PC connection	**Two dedicated Giga-Ethernet channels: one for the machine communication and for the ceph detector, the second dedicated to the PAN/3D detector**	Ethernet for the machine communication + point to point dedicated giga-ethernet for the detector
User interface	**Onboard keyboard and virtual control panel (on PC)**	Onboard keyboard and virtual control panel (on PC)
Software		
System architecture	**Based on multiple CPUs connected via Can Bus plus Ethernet connection to PC**	Based on multiple CPUs connected via Can Bus plus Ethernet connection to PC.

	Proposed device: **X-MIND prime 3D**	**Primary predicate device:** **X-MIND prime 3D** **(Rotograph Prime 3D)**
Firmware functions (of Control Processing Units) for controlling movements and image acquisition/synchronization	**Firmware functions are designed to manage the panoramic/3D version and the cephalometric option. Some differences in the firmware functions are related to the management of the added cephalometric option. Some additional differences are related to specific hardware solutions or different microprocessors from the Primary Predicate Device.**	Firmware functions are designed to manage the following configuration: panoramic/3D version
X-ray generator board firmware functions	**X-ray parameters (kV, mA, pulsed / continuous emission) management, X-ray start and stop, errors control.** **Can Bus communication.**	X-ray parameters (kV, mA, pulsed / continuous emission) management, X-ray start and stop, errors control. Can Bus communication.
Communication protocol between the computer and Controlling Processing Unit board.	**Proprietary TCP/IP protocol**	Proprietary TCP/IP protocol
Software functions (on PC)	**Graphical user interface (GUI) to control the machine, TCP/IP communication, image acquisition and correction; image reconstruction.**	Graphical user interface (GUI) to control the machine, TCP/IP communication, image acquisition and correction; image reconstruction

	Proposed device: X-MIND prime 3D	**Primary predicate device: X-MIND prime 3D (Rotograph Prime 3D)**
Image acquisition	**Integration of the specific detector manufacturer SDK; PC memory and disk space management and control.**	Integration of the specific detector manufacturer SDK; PC memory and disk space management and control.
Image correction (defect map, offset and flat field)	**Correction functions for detector are designed by Acteon / Owandy. Offset correction is done before each acquisition**	**Correction functions for detector are designed by Acteon / Owandy. Offset correction is done before each acquisition**
2D examination programs' final image	**The frames acquired by the Flat panel detector in area mode after the corrections, are elaborated with a shift and add procedure to form the final image. This procedure applies to cephalometric images too**	The frames acquired by the Flat panel detector in area mode are after the correction, are elaborated with a shift and add procedure to form the final image
2D examination programs' image pre-processing	**GUI provides basic image pre-processing capabilities that the user can enable or disable. By default they are disabled. This procedure applies to cephalometric images too**	GUI provides basic image pre-processing capabilities that the user can enable or disable. By default they are disabled.

	Proposed device: **X-MIND prime 3D**	**Primary predicate device:** **X-MIND prime 3D** **(Rotograph Prime 3D)**
3D examination image reconstruction	**The frames acquired by the Flat panel detector in area mode after the correction, are elaborated with a Feldkamp algorithm -and eventually with the MAR algorithm- to get a set of axial slices; then a dicom header is added to each slice file. Dicom dataset is then saved to disk for transfer to external visualization/processing programs.** **The 3D reconstruction is done using PC GPU or CPU.**	The frames acquired by the Flat panel detector in area mode after the correction, are elaborated with a Feldkamp algorithm –and eventually with the MAR algorithm- to get a set of axial slices; then a dicom header is added to each slice file. Dicom dataset is then saved to disk for transfer to external visualization/processing programs. The 3D reconstruction is done using PC CPU.
Installation		
Telescopic column	**Yes**	Yes
Power supply voltage	**110-240 V, 50/60 Hz**	110-240 V, 50/60 Hz
Current rating	**14 A**	14.5 A

Table 7: Comparison between the proposed and the primary predicate device.

The following table is focused on the comparison about the cephalometric exams between the proposed device and the additional predicate device.

	Proposed device: X-MIND prime 3D	**Additional predicate device: DENTIOIII series (DENTIOIII, DENTIOIII-S)**
Cephalometric imaging detector		
Detector model	**Xineos-2301**	Xineos-2301
Manufacturer	**Teledyne DALSA**	Teledyne DALSA
Technology	**CMOS flat panel with Cesium Iodide (CsI) scintillator screen**	CMOS flat panel with Cesium Iodide (CsI) scintillator screen
Sensor active area (Height x Width)	**228 mm x 6.7 mm**	228 mm x 7.0 mm
Pixel size	**99 µm x 99 µm**	99 µm x 99 µm
Bit depth	**14 bit**	14 bit
Number of sensor pixels	**2304 x 68**	2305 x 68
MTF	**65% at 1 lp/mm**	65% at 1 lp/mm
DQE	**57% at 1 lp/mm**	57% at 1 lp/mm
Cephalometric examination programs		
Exam time	**Max 15.1 s (HD) / min 4.4 s (HS)**	Max 8.2 s (Normal) / 4.2 s (Fast)
Frontal (AP/PA) projection	**Yes**	Yes
Lateral (LL) projection	**Yes**	Yes

	Proposed device: X-MIND prime 3D	**Additional predicate device: DENTIOIII series (DENTIOIII, DENTIOIII-S)**
Carpus	**Yes**	Yes
Mechanical characteristics		
Source to image distance	**1650 mm**	1735 mm (single detector type) 1729 mm (dual detector type)
Type of installation	**Floor-Wall or Floor mount**	Floor mount
Weight (wall mount version)	**123 kg**	160 kg
Dimensions (wall mount version)	**2229.5 mm x 1851 mm x 1205 mm**	2309 mm x 1953 mm x 1222 mm

Table 8: Comparison between the proposed and the additional predicate device.

The differences between the proposed device and the predicate devices do not raise new questions of safety and effectiveness.

VII. PERFORMANCE DATA AND TESTING EVIDENCE

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

Electrical safety and EMC testing were conducted on X-MIND prime 3D.
The performance tests were 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 and dental extra-oral X-ray equipment
- compliance with usability requirements
- compliance with electromagnetic compatibility requirements.

The following table shows the standards to which X-MIND prime 3D complies, compared to those related primary predicated device X-MIND prime 3D:

Applied standards	Proposed device: X-MIND prime 3D	Primary predicate device: X-MIND prime 3D (Rotograph Prime 3D)
	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
	IEC 60601-1-2:2014	IEC 60601-1-2:2007
	IEC 60601–1–3:2013	IEC 60601–1–3:2008
	IEC 60601-2-63:2017	IEC 60601-2-63:2012
	IEC 62304:2015	IEC 62304:2006
	ES60601-1: 2005/(R)2012 and A1:2012	ANSI/AAMI ES60601-1: 2005 / A2:2010
	CAN/CSA-C22.2 No. 60601-1:08	CAN/CSA-C22.2 No. 60601-1:08
	IEC 60601-1-6:2013	IEC 60601-1-6:2010
	IEC 62366-1:2015	IEC 62366:2007
	ISO 10993-1:2010	ISO 10993-1:2010
	ISO 10993-2:2006	ISO 10993-2:2006
	ISO 10993-5:2009	ISO 10993-5:2009
	ISO 10993-10:2010	ISO 10993-10:2010
	ISO 10993-12:2012	ISO 10993-12:2012

X-MIND prime 3D 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.

VIII. CONCLUSION

X-MIND prime 3D has the same indication for use as the predicate devices. It performs the same functions in the same environment as the predicate devices. It is based on well-known technology. It shares the same technological characteristics as the predicate devices. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device, so it is as safe as effective as the predicate devices.