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

February 5, 2021

Re: K203374
Trade/Device Name: X-MIND prime (under trade mark Acteon), I-MAX (under trade mark Owandy Radiology)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: November 9, 2020
Received: November 16, 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)*
K203374

Device Name
X-MIND prime (under trade mark Acteon)
I-MAX (under trade mark Owandy Radiology)

Indications for Use *(Describe)*
X-MIND prime (and I-MAX under trade mark Owandy Radiology) is an extra-oral dental panoramic X-ray unit to take two dimensional radiographic exams of teeth, jaw and oral structures (panoramic, TMJ and sinus exams). 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. 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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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:	November 9th, 2020

Table 1: Submitter information

II. PROPOSED DEVICE

Name of the device:	X-MIND prime (under trademark Acteon) I-MAX (under trademark Owandy Radiology)
Common or Usual name:	Dental panoramic and cephalometric system
Classification name:	Extraoral source X-ray system (21 CFR 872.1800)
Regulatory class:	II
Product Code:	MUH

Table 2: Proposed device information

III. PREDICATE DEVICE and REFERENCE DEVICES

Legally marketed devices to which equivalence is claimed is:

PREDICATE DEVICE	
Device name	Rotograph Evo D
Manufacturer	Villa Sistemi Medicali
Device product code	MUH
Regulation number	872.1800
Regulation name	Extraoral source x-ray system
Clearance date	May 18th, 2009
510(k) number	K090749

Table 3: Predicate device information

REFERENCE DEVICE #1	
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: Reference device #1 information

REFERENCE DEVICE #2	
Device name	Rotograph Prime (New proprietary name X-MIND prime)
Manufacturer	de Götzen S.r.l. – ACTEON Group
Device product code	MUH
Regulation number	872.1800
Regulation name	Extraoral source x-ray system
Clearance date	July 6th, 2017
510(k) number	K162190

Table 5: Reference device #2 information

IV. DEVICE DESCRIPTION

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

X-MIND prime is an X-ray device for the radiographic analysis of the maxillo-facial complex.
X-MIND prime performs Panoramic, Half-panoramic, Low dose Panoramic, Frontal dentition, Ortho Rad Panoramic, Bitewing Bilateral, Bitewing Left and Bitewing Right, Sinus, TMJ, AP and LL cephalometric exams, Carpus exam.

X-MIND prime 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 device (listing number D342124 and FDA clearance K162190).
This significant change mostly consists in the addition of the cephalometric arm to X-MIND prime, as shown in overview figure below:

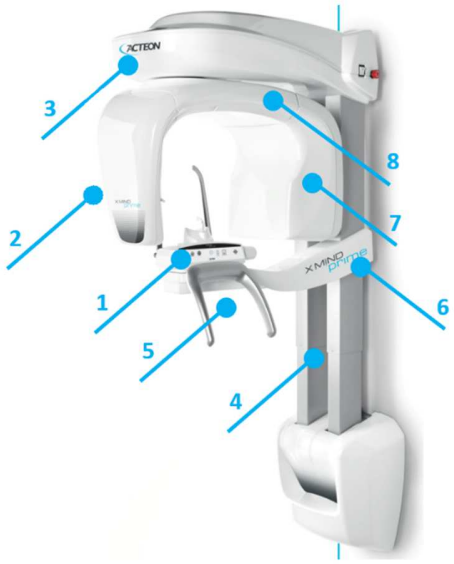
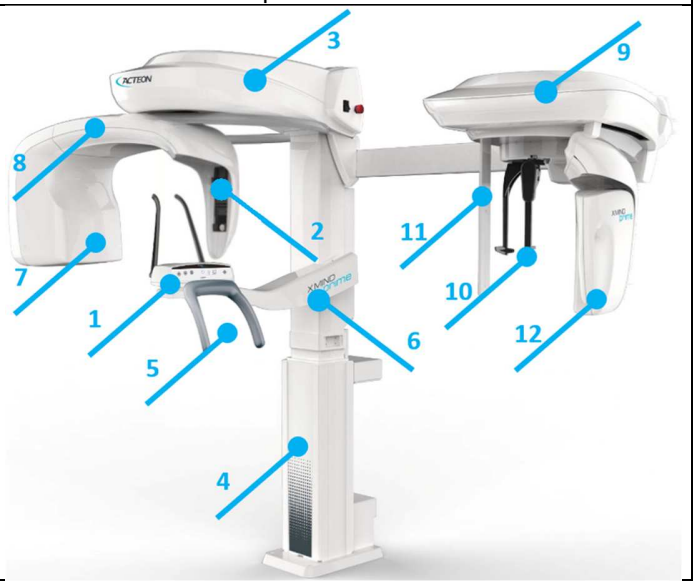
X-MIND prime without CEPH arm	X-MIND prime with CEPH arm
	

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

X-MIND prime 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/CEPH detector for the acquisition of the radiographic images of the maxillo-facial region. When placed on the rotating arm, the detector is ready for the acquisition of panoramic images. Further, the detector can be moved from the rotating arm to the cephalometric arm in order to perform the cephalometric examinations.
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 the detector and the X-ray generator. This is the rotating part of the medical device, which moves around the patient during the image acquisition phase of panoramic exams.
9	CEPH arm	In the version of X-MIND prime 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	Detector	When mounted on the cephalometric arm, 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 6: X-MIND prime parts

EQUIPMENT CONFIGURATIONS

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

PAN

In this configuration, X-MIND prime is equipped only with the PAN detector which allows to acquire the panoramic exams.

PAN / CEPH

The equipment can carry out the panoramic and cephalometric exams.
The device is equipped with a PAN/CEPH detector which allows to acquire both panoramic and cephalometric exams. The PAN/CEPH detector can be moved from the rotating arm to the cephalometric arm and viceversa, according to the type of exam to be performed.

LIST OF EXAMS

X-MIND prime 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

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 pre-set 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/CEPH) are the most important parts of the X-MIND prime device and allow the acquisition of the radiographic images of the maxillofacial complex. The PAN/CEPH detector and the X-ray source are mounted on the rotating arm of the device. The detector can be moved from the rotating arm to the cephalometric arm when the cephalometric examinations must be acquired.

During the panoramic 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 panoramic image.

In order to acquire the cephalometric exams, the detector performs a horizontal linear scanning of the skull, while the focus is kept in a fixed position and 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 (and I-MAX under trade mark Owandy Radiology) is an extra-oral dental panoramic X-ray unit to take two dimensional radiographic exams of teeth, jaw and oral structures (panoramic, TMJ and sinus exams). 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. 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 and REFERENCE DEVICES

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

	Proposed device: X-MIND prime	**Predicate device: Rotograph Evo D**	**Reference device #1: DENTIOIII series (DENTIOIII, DENTIOIII-S)**	**Reference device#2: Rotograph Prime**
Intended Use	X-MIND prime is an extra-oral dental panoramic X-ray unit to take two dimensional radiographic exams of teeth, jaw and oral structures (panoramic, TMJ and sinus exams). 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 Evo D, panoramic x-ray imaging systems with cephalostat, are extraoral source x-ray systems, which are intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry.		Rotograph Prime is an extra-oral dental panoramic X-ray unit to radiograph teeth, jaw and oral structures.

	Proposed device: X-MIND prime	**Predicate device: Rotograph Evo D**	**Reference device #1: DENTIOIII series (DENTIOIII, DENTIOIII-S)**	**Reference device#2: Rotograph Prime**
	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		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	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 7: Comparison of the intended use among proposed and predicate devices.

Detailed comparison of similarities and differences

The intended use of the proposed device and of the predicate device are the same:

They have the same functions in the same environment. in particular, the proposed device performs the same exams for the examination of teeth, jaw, oral structures, cranial cephalometric exams in different projections and the wrist exam

The intended use of the proposed device is taken from labelling (operator's manual) for this reason it is intended to be explicative and as detailed as possible to be clear for the intended user, the intended use of Rotograph Evo D, is taken from "Indications for use" available in K090749 Summary and it is more synthetic in the form but it covers all the proposed device intended use

The following table highlights the existing similarities between the proposed device and the predicate device.

	Proposed device: X-MIND prime	**Predicate device: Rotograph Evo D**
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)	**1.23 constant**	1.23 constant

	Proposed device: X-MIND prime	**Predicate device: Rotograph Evo D**
Source to image distance	**500 mm**	500 mm
Magnification (cephalometric)	**1.1 constant**	1.1 constant
Source to image distance (cephalometric)	**1650 mm**	1650 mm
Panoramic max image size	**equivalent to 15x30 cm film**	equivalent to 15x30 cm film
Adult panoramic scan time	**14 sec**	13.8 sec
Child panoramic exam with shorter scan time than adult panoramic exam	**12.8 sec**	13.8 sec
Cephalometric image sizes	**From 18 x 18 to 24 x 30 (height x width)**	24 x 18 to 24 x 30 (height x width)
Cephalometric scan time	**From 4.4 s to 15.1 s depending on image size**	From 4.5 s to 15 s depending on image size
Generator/tube characteristics		
X-ray generator	**High frequency**	High frequency
Focal spot value	**0.5 mm (IEC 60336)**	0.5 mm (IEC 60336)
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

	Proposed device: X-MIND prime	**Predicate device: Rotograph Evo D**
kV Range	**60 - 86 kV step 2kV**	60 - 86 kV step 2kV
Total filtration	**2.5 mm Al eq**	2.5 mm Al eq
Collimator	**Automatic**	Automatic
mA range	**2 - 12.5 mA**	6 - 12 mA
Patient positioning		
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**	Temple clamps, bite block, chin support
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
Patient positioning tools in cephalometric exams	Ear rods, nasion support	Ear rods, nasion support
User interface		
PC connection	**Dedicated Giga-Ethernet channel**	Ethernet connection
User interface	**Onboard keyboard and virtual control panel (on PC)**	Onboard keyboard with touchscreen and virtual control panel (on PC)

	Proposed device: **X-MIND prime**	**Predicate device:** **Rotograph Evo D**
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. In this case, the device has two more CPUs for controlling the onboard GUI and vertical column
Firmware functions (of MCU and CCU Control Processing Units) for controlling movements and image acquisition/synchronization	**Firmware functions are designed to manage the panoramic version and the cephalometric option. Some differences are related to specific hardware solutions or different microprocessors from the Predicate Device.**	Firmware functions are designed to manage the following configurations: Film Version, digital panoramic version, cephalometric option
X-ray generator board firmware functions	**X-ray parameters (kV, mA) management, X-ray start and stop, errors control.** **Can Bus communication.**	X-ray parameters (kV, mA) 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

	Proposed device: **X-MIND prime**	**Predicate device:** **Rotograph Evo D**
Image acquisition	**Integration of the specific detector manufacturer SDK;** **PC memory and disk space management and control.**	Integration of a proprietary detector 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 are designed by Acteon / Owandy. Offset correction is done before each acquisition
2D examination programs' final image	**The frames acquired by the detector in area mode after the corrections, are elaborated with a shift and add procedure to form the final image emulating the TDI (Time Delay Integration) acquisition mode**	The detector acquires images directly in TDI mode, then the software applies the correction explained in the previous table raw 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.
Installation		
Telescopic column	**Yes**	Yes
Power supply voltage	**110-240 V, 50/60 Hz**	110-120 V, 50/60 Hz
Current rating	**14 A**	15 A

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

The following table is focused on the comparison between the proposed device and the reference device #1.

DENTIOIII series (DENTIOIII, DENTIOIII-S): it is taken in the version with cephalometric arm (DENTIOIII-S) as reference device #1, manufactured by HDX WILL CORP. and cleared by FDA with 510(k) number K181297. The proposed device and the reference device share the same digital acquisition sensor for the cephalometric examinations.

	Proposed device: X-MIND prime	**Reference device #1: DENTIOIII series (DENTIOIII, DENTIOIII-S)**
Panoramic / 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
Panoramic examination programs		
Panoramic exam time	**14 s**	14.2 s

	Proposed device: X-MIND prime	**Reference device #1: DENTIOIII series (DENTIOIII, DENTIOIII-S)**
Panoramic exam	**Yes**	Yes
TMJ exam	**Yes**	Yes
Sinus exam	**Yes**	Yes
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
Carpus	**Yes**	Yes
Mechanical characteristics		
Source to image distance in panoramic exams	**500 mm**	535 mm
Source to image distance in cephalometric exams	**1650 mm**	1735 mm (single detector type) 1729 mm (dual detector type)
Type of installation	**Floor-Wall mount**	Floor mount
Weight (wall mount version)	**118 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 9: Comparison between the proposed and the reference device #1.

To demonstrate that the quality of cephalometric images, acquired by X-MIND prime, is adequate for clinical purpose, we have provided a study evaluating images taken with proposed device performed by an independent reviewer graduated in Dentistry and Dental Prosthetics and Orthognathic

The following table is focused on the comparison between the proposed device and the reference device #2. X-MIND prime (Rotograph Prime) cleared with K162190

The proposed device and the reference device #2 share the same intended use excluded the cephalometric application and some technical details; moreover the reference device #2 has a Child specific panoramic exam with a shorter scan time as the proposed device.
To establish the equivalence of the image quality between the two devices we have performed a specific Performance Testing – Bench.

	Proposed device: X-MIND prime	**Reference device #2: Rotograph Prime**
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

	Proposed device: X-MIND prime	**Reference device #2: Rotograph Prime**
2D Examination characteristics		
Magnification (Panoramic)	**1.23 constant**	1.23 constant
Source to image distance (panoramic)	**500 mm**	500 mm
Panoramic max image size	**equivalent to 15x30 cm film**	equivalent to 15x30 cm film
Adult panoramic scan time	**14 sec**	14.4 sec
Child panoramic exam with shorter scan time than adult panoramic exam	**12.8 sec**	13.3 sec
Patient positioning		
Height adjustment	**Motorized**	Motorized
Positioning lights in panoramic exams	**2 laser pointers**	2 laser pointers
Patient position	**Standing**	Standing
Patient positioning tools in panoramic exams	**Temple clamps, bite block, chin support**	Temple clamps, bite block, chin support
Focal layer adjustment (prognatism compensation)	**Electronic, three positions, no patient movement**	Electronic, three positions, no patient movement
Patient positioning orientation vs the operator in panoramic exams	**Face to face**	Face to face
Height of chin support from the floor	**978-1678 mm**	975-1635 mm

	Proposed device: X-MIND prime	**Reference device #2: Rotograph Prime**
User interface		
PC connection	**Dedicated Giga-Ethernet channel**	Ethernet connection
User interface	**Onboard keyboard and virtual control panel (on PC)**	Onboard keyboard and virtual control panel (on PC)

Table 10: Comparison between the proposed and the reference device #2.

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.
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 complies, compared to those related predicated device Rotograph Evo D:

Applied standards	
Proposed device: X-MIND prime	Predicate device: Rotograph Evo D
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 10993-2:2006	
ISO 10993-5:2009	
ISO 10993-10:2010	
ISO 10993-12:2012	

To assess the quality of the child panoramic images acquired with the proposed device X-MIND prime (PAN/CEPH version) and the reference device#2: Rotograph Prime (PAN version) in order to establish

the equivalence of the image quality between the two devices we have performed a specific bench test

X-MIND prime 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.

VIII. FDA GUIDANCE DOCUMENTS

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

- FDA Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s dated September 2019
- FDA Guideline Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"dated September 2020
- FDA Guideline Recomended Content and format of complete Test reports for NOn-ClinicalBench performance Testing in 510K submission dated December 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 dated May 2005
- FDA Guidance Content of premarket submission for management of cybersecurity October, 2014

IX. CONCLUSION

X-MIND prime has the same indication for use as the predicate and reference device #1. It is based on well-known technology. It shares the same technological characteristics as the predicate and reference devices. It has been tested on the basis of recognized standards and special controls 21 CFR §1020.30, 21 CFR §1020.31.
Minor technological differences,
given results of risk analysis of the changes of X-MIND prime with cephalometric option respect to the predicate device

given results of performance bench with reference device #2,
do not raise any new questions regarding safety or effectiveness of the device, so it is as safe and effective as the predicate device.