Villa Sistemi Medicali S.p.A.
Paolo Casagrande Santin
Quality Assurance Manager
via delle Azalee 3
20090 BUCCINASCO (MI)
ITALY

November 2, 2018

Re: K180601
Trade/Device Name: Rotograph Prime 3D (under Trade mark Villa Sistemi Medicali), I-MAX 3D (under Trade mark Owandy Radiology)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: October 12, 2018
Received: October 19, 2018

Dear Paolo Casagrande Santin:

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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

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)*
K180601

Device Name
Rotograph Prime 3D, I-MAX 3D

Indications for Use *(Describe)*
Rotograph Prime 3D and I-MAX 3D are extra-oral dental panoramic and CBCT (aka CBVT) X-ray units to take either two dimensional (panoramic, TMJ and sinus exams) or three dimensional radiographic exams of teeth, jaw and oral structures.

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 devices are operated and used by dentists, radiologists and other legally qualified health care professionals.

They can be used with both pediatric and adult patients.

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

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

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Date Prepared: October 12, 2018

Subject Device

510(k) number:	K180601
Trade Name:	Rotograph Prime 3D (under trade mark Villa Sistemi Medicali) I-MAX 3D (under Trade mark Owandy Radiology as Private Labeler)
Device Type:	x-ray, tomography, computed, dental
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Regulatory Class:	Class II
Product Code:	OAS

Primary Predicate Device

Trade Name:	I-MAX Touch 3D
Manufacturer:	Owandy Radiology
510(k) clearance:	K130443 (June 14, 2013)
Device Type:	x-ray, tomography, computed, dental
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Regulatory Class:	Class II
Product Code:	OAS

Additional Predicate Device	Trade Name:	Rotograph Prime
	Manufacturer:	Villa Sistemi Medicali S.p.A.
	510(k) clearance:	K162190 (July 6, 2017)
	Device Type:	System, x-ray, extraoral source, digital
	Regulation Number:	21 CFR 872.1800
	Regulation Name:	Extraoral Source X-Ray System
	Regulatory Class:	Class II
	Product Code:	MUH

Device Description

Rotograph Prime 3D (and I-MAX 3D under trade mark Owandy Radiology) is a complete 3D and 2D panoramic X-ray system. It performs:

2D standard examination programs

- Standard Panoramic: adult/child panoramic exam
- TMJ open and closed mouth
- Sinus P/A projection
- Half Panoramic (left/right)
- Ortho Rad Panoramic
- Frontal Dentition
- Low Dose Panoramic
- Bitewing (Left/Right/Left and Right

3D standard examination programs

- 3D Full Dentition
- 3D Single Jaw (Maxillary, Mandibular)
- 3D Mandibular Teeth (Frontal, Premolars and Molars)
- 3D Maxillary Teeth (Frontal, Premolars and Molars)
- 3D TMJ ((right/left)
- 3D Sinus

The images are acquired by a CMOS Flat Panel detector with CsI scintillator and are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer (not included in the device).

Installation mode

The subject device is sold in wall or floor mounted version.

Accessories and components

The device can be equipped with different accessories to fulfill different diagnostic needs, such as three different chin supports with bite stick or with special removable appendix for edentulous patients, specific support for 2D TMJ exam, head strips for 3D exams and X-ray push button with extensible.

The device contains the following materials and/or components:

- Tube-head: dielectric oil, copper, iron, aluminum, glass, tungsten.

- Collimator: lead
- Other parts of the device: non-biodegradable plastic materials, metal materials, printed circuits, iron-plastic materials, lead

The patient contacting components are:

- temple support rods
- chin supports
- bite sticks
- head strips
- handles

Chin supports, bite sticks are unchanged from primary predicate device, and temple support rods and handles are unchanged from additional predicate device.

Head strips and all other parts in contact with patient have been assessed according to ISO 10993.

Contact duration is in the range of seconds to few minutes and contact type is surface-contacting.

Indication for Use

Rotograph Prime 3D (and I-MAX 3D under trade mark 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.

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.

Rationale for Substantial Equivalence

Here below a summing up the main features of the proposed and predicate devices in order to point out the significant similarities and differences.

Rotograph Prime 3D (and I-MAX 3D under trade mark Owandy Radiology) is based on a well-known technology and it has the same indication for use as the predicate devices as reported here below.

	Proposed device: Rotograph Prime 3D and I-Max 3D	Primary predicate device: I-MAX Touch 3D	Additional predicate device: Rotograph Prime
Intended Use	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. 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.	I-MAX Touch 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBVT technique, to generate dento-maxillofacial 3D images. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. 2D Images are obtained using the standard narrow beam technique The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals.	Rotograph Prime is an extra-oral dental panoramic X-ray unit to radiograph teeth, jaw and oral structures. 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.

The following tables list the similarities and the differences between the subject device (Rotograph Prime 3D under trade mark Villa Sistemi Medicali and I-MAX 3D under trade mark Owandy Radiology) and the primary predicate device I-MAX Touch 3D, and the additional predicate device Rotograph Prime.

A detailed discussion about the differences is reported in section "Substantial Equivalence Discussion"

Similarities

	Proposed device (Rotograph Prime 3D)	Primary predicate device (I-MAX Touch 3D)	Additional Predicate Device (Rotograph Prime)
2D Examination programs			
Panoramic exam	**Yes**	Yes	Yes
Ortho Rad Panoramic	**Yes**	Yes	Yes
Segmented Panoramic (Half panoramic, frontal dentition, bitewings)	**Yes**	Yes	Yes

	Proposed device (Rotograph Prime 3D)	**Primary predicate device (I-MAX Touch 3D)**	**Additional Predicate Device (Rotograph Prime)**
Low dose panoramic	**Yes**	Yes	Yes
TMJ Open/Closed mouth	**Yes**	Yes	Yes
TMJ single phase	**Yes**	Yes	Yes
Sinus	**Yes**	Yes	Yes
Cephalometric option available	**NO**	YES	NO
2D Exam characteristics			
Panoramic max image size	**equivalent to 15x30 cm film**	equivalent to 13x30 cm film	equivalent to 15x30 cm film
3D examination programs			
3D Full dentition	**Yes**	Yes	n/a
3D TMJ Left	**Yes**	Yes	n/a
3D TMJ Right	**Yes**	Yes	n/a
3D sinus	**Yes**	Yes	n/a
3D Single Jaw (maxillary / mandibular)	**YES**	NO	n/a
3D teeth only (maxillary / mandibular)	**YES**	NO	n/a
3D High resolution mode	**YES**	NO	n/a
3D exam characteristics			
X-ray beam	**cone beam**	cone beam	n/a
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)	n/a
Reconstruction algorithm	**Feldkamp with the option of MAR (Metal Artifact Removal)**	Feldkamp with the option of MAR (Metal Artifact Removal)	n/a
Generator/tube characteristics			
X-ray generator	**High frequency**	High frequency	High frequency
Focal spot value	**0.5 mm (IEC 60336)**	0.5 mm (IEC 60336)	0.5 mm (IEC 60336)

	Proposed device (Rotograph Prime 3D)	Primary predicate device (I-MAX Touch 3D)	Additional Predicate Device (Rotograph Prime)
Independent kV-mA regulation	**YES**	YES	YES
DAP Software	**YES**	YES	YES
kV Range	**60 - 86 kV step 2kV**	60 - 86 kV step 2kV	60 - 70 kV step 2kV
Total filtration	**2.5 mm Al eq**	2.5 mm Al eq	2.0 mm Al eq
Collimator	**Automatic**	Automatic	Fixed
Patient positioning			
Height adjustment	**motorized**	motorized	motorized
Positioning lights	**2 laser pointers**	2 laser pointers	2 laser pointers
Patient position	**Standing**	Standing	Standing
Patient positioning tools	**temple clamps, bite block, chin support, head strip**	temple clamps, bite block, chin support, head strip	temple clamps, bite block, chin support
Height of chin support from the floor	**975-1635 mm**	920-1755 mm	975-1635 mm
Patient positioning orientation vs the operator	**face to face**	lateral with adjustable mirror	face to face
User interface			
Real time visualization	**YES**	YES	YES
User interface	**Onboard keyboard and virtual control panel (on PC)**	Onboard keyboard and O-LED display, plus virtual control panel (on PC)	Onboard keyboard and virtual control panel (on PC)
Installation			
Power supply voltage	**110-120 V, 50/60 Hz**	110-120 V, 50/60 Hz	110-120 V, 50/60 Hz
Current rating	**14.5 A**	15 A	7 A
Type of installation	**wall or floor mount**	Wall or floor mount	Wall mount
Weight (wall mount version)	**67 kg**	161 kg	62 kg
Dimensions (wall mount version)	**2184mm x 1107 mm x 953 mm**	2450 mm x 1260 mm x 1040 mm	2184mm x 1107 mm x 953 mm

Differences

	Proposed device (Rotograph Prime 3D)	Primary predicate device (Rotograph Evo 3D)	Additional Predicate Device (Rotograph Prime)
3D examination programs			
3D Single Jaw (maxillary / mandibular)	**YES**	NO	n/a
3D teeth only (maxillary / mandibular)	**YES**	NO	n/a
3D High resolution mode	**YES**	NO	n/a
3D exam characteristics			
Biggest FOV (Ø x H) mm (3D dentition, 3D TMJs, 3D sinus)	**85 mm x 93 mm**	85 mm x 85 mm	n/a
3D Imaging detector			
Technology	**CMOS flat panel with Cesium Iodide (CsI) scintillator screen**	Amorphous Silicon with Cesium Iodide (CsI) scintillator screen	n/a
Sensor active area (Height x Width)	**144 mm x 119.5 mm**	130 mm x 130 mm	n/a
Pixel size	**120 µm x 120 µm**	127 µm x 127 µm	n/a
Bit depth	**16 bit**	14 bit	n/a
Generator/tube characteristics			
mA range	**2 - 12.5 mA**	6 - 10 mA	2 – 7.1 mA

Rotograph Prime 3D (and I-MAX 3D under trade mark Owandy Radiology) has the same functions in the same environment as the primary predicate device I-MAX Touch 3D and the additional predicate device Rotograph Prime (and I-MAX under trade mark Owandy Radiology).

Specifically, the proposed device performs the same projections for the 2D examination of teeth, jaw and oral structures as both I-MAX Touch 3D and Rotograph Prime (and I-MAX under trade mark Owandy Radiology) and in addition has the capability to perform three dimensional exams as I-MAX Touch 3D device. On the proposed device, in addition to the exams present on I-MAX Touch 3D, has been added some new smaller field of view 3D examinations derived from the correspondent examinations with full field of view.

The proposed device uses a high frequency x-ray generator with the same electronics and x-ray exposure control as Rotograph Prime (and I-MAX under trade mark Owandy Radiology), with a range of exposure parameters similar to that of I-MAX Touch 3D. The focal spot value is the same as both predicate devices. The range of mA has been extended to the lower values allowing further dose reduction and to higher values allowing a reduction of the exam exposure time (still preserving the overall patient's dose).

In the proposed device the patient positioning is assured by two laser pointers that allow to locate the patient reference planes as in both predicate devices and is frontal as in Rotograph Prime. The range of chin support height is the same as Rotograph Prime one.

The proposed device's detector is based on the same principle of the primary predicate device I-MAX Touch 3D (large area flat panel detector), however it's a more recent product; small differences are in the pixel size and active area. The equivalence of the image quality of both two dimensional and three dimensional radiographic exams of the proposed device vs the primary predicate device has been assessed with image comparison tests.

The user interface of the proposed device is the same as in Rotograph Prime and equivalent to that of I-MAX Touch 3D.

COMPARISON OF KEY IMAGE QUALITY METRICS along with dose between the subject and primary predicate device

		Proposed device Rotograph Prime 3D	Primary predicate device I-MAX Touch 3D
Panoramic mode			
Spatial resolution		3 lp/mm	2.2 lp/mm
Contrast resolution (number of visible holes in the phantom defined in IEC 61223-3-4)		4	4
DAP		@80kV 9mA 14.0s: 15.7 uGy·m^2	@80kV 9mA 13.8s: 13.0 uGy·m^2
3D mode			
Nyquist Frequency		2.85 lp/mm	2.7 lp/mm
Contrast to Noise Ratio	*Metrics defined in standard DIN6868-161*	15.3	17.9
Homogeneity		8.6	7.0
MTF on axial slices		10% modulation: 1.37 lp/mm 50% modulation: 0.72 lp/mm	10% modulation: 1.31 lp/mm 50% modulation: 0.57 lp/mm
Acceptance Index		247 (mGy·cm^2)$^{-1}$	86 (mGy·cm^2)$^{-1}$
DAP (3D full dentition)		@84kV 5mA 7s: 108 uGy·m^2	@80kV 8mA 11.2s: 196.7 uGy·m^2

In the panoramic mode of operation the DAP value is slightly higher for the subject device. This is substantially due to the higher vertical size of the detector (14.2mm high, compared to 12.8mm of the primary predicate device), allowing to have a larger field of view and anatomic coverage.

In the 3D mode of operation instead, on the subject device the default parameters for a standard adult patient are chosen so to give priority to the dose containment with respect to the predicate device, at the cost of a slightly higher

image noise that results in a lower Contrast to Noise Ratio as explained in detail in the Test Report RT336_2018-08-31_rev0_imageQuality included in Annex L. The user can anyway increase the radiological parameters in order to obtain higher contrast, should the need arise. This choice is also supported by the fact that the Acceptance Index is much higher in value, indicating an overall better performance. In fact Acceptance Index (defined in the standard DIN6868-161) is a parameter that indicates that the overall imaging performance, taking into account both the delivered dose, the image resolution and image contrast. The higher is the value the better is the device performance vs the delivered dose. Additional details are given in above mentioned annex.

COMPARISON OF SOFTWARE between the subject and predicate device

	Proposed device Rotograph Prime 3D	**Primary predicate device I-MAX Touch 3D**	
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	The firmware architecture is the same as the Predicate Devices. The architecture and number of CPUS of the Proposed Device are simplified compared to the primary predicate device due to: - Elimination of onboard GUI - Replacement of column movement device with a component not requiring a CPU (fully hardware-implemented)

	Proposed device Rotograph Prime 3D	Primary predicate device I-MAX Touch 3D	
Firmware functions (of MCU and DSPU Control Processing Units) for controlling movements and image acquisition/synchronization	**Firmware functions are designed to manage the panoramic/3D version, which is considered a subset of the versions in the primary predicate device. The number of 3D exams is greater, but their management is the same in terms of firmware. Some differences are related to specific hardware solutions or different microprocessors from the Primary Predicate Device.**	Firmware functions are designed to manage the following configurations: Film Version, digital panoramic version, panoramic/3D version, cephalometric option	The firmware functions of the proposed device are equivalent to those of the Primary Predicate device, some functions have been eliminated since the proposed device has just a machine version. The fact that proposed device has more 3D exams available doesn't add complexity to the firmware.
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.	Firmware functions and Can Bus protocol are the same as in the Primary Predicate device
Communication protocol between the computer and DSPU board.	**Proprietary TCP/IP protocol**	Proprietary TCP/IP protocol	The communication protocol is the same as the Primary Predicate Device one.
Software functions (on PC)	**Graphical use interface (GUI) to control the machine, TCP/IP communication, image acquisition and correction; image reconstruction.**	Graphical use interface (GUI) to control the machine, TCP/IP communication, image acquisition and correction; image reconstruction	Software functions are the same as Primary Predicate Device one; the GUI is different in the graphics respect to the Primary Predicate device but is the same to the Additional Predicate Device, with a wider selection of exam options.

	Proposed device Rotograph Prime 3D	Primary predicate device I-MAX Touch 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.	Proposed Device and Primary Predicate Device use imaging detector of different manufacturers so SDK are different but PC memory and disk space management and control is the same as Primary Predicate Devices
Image correction (defect map, offset and flat field)	**Correction functions for detector in area mode are designed by Villa / Owandy. Offset correction is done before each acquisition**	Correction functions are provided by the detector manufacturer. Offset correction is done before each acquisition	Correction functions implemented are standard functions of offset subtraction, flat field correction and defect map correction and they are equivalent to those provided by the Primary Predicate Device detector manufacturer.
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**	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	Same as predicate device
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.**	No image processing is available	This function has been added respect to the Primary Predicate Device but it is already present on the Additional Predicate Device.

	Proposed device Rotograph Prime 3D	Primary predicate device I-MAX Touch 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.	The algoritm to calculate the slices of the 3D studies is the same as the predicate device one. Small differences are related to the algorithm tuning for the different pixel size, detector size and detector response and for the presence of partial and high resolution volumes. The algorithm has been implemented to run on the computer CPU and on the graphic card GPU. The algorithm on GPU verification is reported in PANOVA - N135C - GPU processing time estimation

Performance Data And Testing Evidence

Electrical safety, EMC/EMI testing, biocompatibility consideration, performance and image quality testing, verification and validation testing were performed to support the substantial equivalence determination. All standards applied were FDA recognized international standards. The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005). The device software is considered a "Moderate Level of Concern".

Rotograph Prime 3D (and I-MAX 3D under trade mark Owandy Radiology) has been designed to be in conformity with the following international standards:

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601–1–3:2008: Medical electrical equipment - Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-63:2012: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
- IEC 62304:2006: Medical device software - Software life-cycle processes
- ANSI/AAMI ES60601-1: 2005 / A2:2010 - Medical electrical equipment, Part 1: General Requirements

- CAN/CSA-C22.2 No. 60601-1:08: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-6:2010: Medical electrical equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability
- IEC 62366:2007: Medical devices – Application of usability engineering to medical devices
- ISO 10993-2:2006: Biological evaluation of medical devices- part 2: animal welfare requirements
- ISO 10993-5:2009: Biological evaluation of medical devices- part 5: tests for in vitro cytotoxicity
- ISO 10993-10:2010: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-12:2012: Biological evaluation of medical devices- part 12: sample preparation and reference materials

In the submission are provided all the test reports including test protocol, methods, pass/fail criteria, and results in conformity with the standards here above.

A risk analysis was performed to analyze the hazards associated with the changes.

Non-clinical considerations according to FDA Guidance "Guidance for the submissions of 510(k)'s for Solid State X-ray Imaging Devices" (September 1, 2016) were performed in order to assess the image quality and the relevant analysis has been supplied, together with specific technical data provided by the supplier of the detector (see Appendix L).

Substantial Equivalence Conclusion

The intended use of the proposed device is the same of the predicate device. Concerning the technical characteristics, it has been demonstrated that Rotograph Prime 3D (and I-MAX 3D under trade mark Owandy Radiology) does not introduce innovative aspects and does not arise different considerations regarding the safety and the relevant risks linked to the device. Non-clinical testing demonstrates that the device performs in a substantially equivalent manner to the predicate devices with regard to imaging and dose performance. Despite some minor technological differences, Rotograph Prime 3D (and I-MAX 3D under trade mark Owandy Radiology) can be considered as safe and as effective as the predicate devices and therefore substantially equivalent to the predicates I-MAX Touch 3D and Rotograph Prime.