DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 6, 2017

VILLA SISTEMI MEDICALI S.P.A.
PAOLO SANTIN
QA MANAGER
VIA DELLE AZALEE 3
BUCCINASCO I-20090
IT

Re: K162190
Trade/Device Name: Rotograph Prime (under Trade Mark Villa Sistemi Medicali), I-max (under Trade Mark Owandy Radiology)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: June 5, 2017
Received: June 8, 2017

Dear Mr. 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. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert A. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162190

Device Name
Rotograph Prime (under Trade Mark Villa Sistemi Medicali), I-MAX (under Trade Mark Owandy Radiology)

Indications for Use *(Describe)*
Rotograph Prime and I-MAX are extra-oral dental panoramic X-ray units to radiograph teeth, jaw and oral structures.
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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - rev. 1

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

Submitter:
Villa Sistemi Medicali S.p.A.
via delle Azalee 3
20090 Buccinasco (MI)
ITALY
Phone: +39 02 488591
Registration # 8021091

Contact Person:
Paolo Casagrande Santin
QA Manager
Phone: +39 02 48859 239
Fax: +39 02 48859 303
Email: p.casagrande@villasm.com

Designated Agent:
Ernesto Filizzola
Villa Radiology Systems
91 Willenbrock Rd. B-1
Oxford, CT, 06478
ph 203 2628836
e-mail ernesto@villaus.com

Date Prepared: June 27, 2017

Device Name: Rotograph Prime (under trade mark Villa Sistemi Medicali)
I-MAX (under Trade mark Owandy Radiology as Private Labeler)

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

Predicate Device: The Rotograph Prime (and I-MAX under trade mark Owandy Radiology) is compared with the following predicate device:

Villa Sistemi Medicali Rotograph EVO D (K090749)
- Regulation Number: 21 CFR 872.1800
- Regulation Name: Extraoral Source X-Ray System
- Regulatory Class: Class II
- Product Code: MUH

Product Description: Rotograph Prime (and I-MAX under trade mark Owandy Radiology) is a complete panoramic X-ray system. The basic version performs:

- Panoramic adult or child exams, with 3 sizes and 3 types of biting for a total of 18 combinations with automatic parameter selection; with manual selection, it is possible to select a high voltage between 60kV and 70kV, in 2kV steps and anodic current from 2 mA to 7.1 mA in the R20 scale steps.
- Sinus mode to take exams of the paranasal sinuses with front projection (postero/anterior);
- TMJ (closed/open mouth) exams in lateral projection.

XP (Extended Projection Package) optional function allows to carry out the following additional exams:

- Right or left half-panoramic, to be used when the patient is known to have a problem only on one side of the arch, in order to reduce radiation;
- Low dose Panoramic, which reduces the dose radiated by excluding the TMJ's ascending rami from the radiograph;
- Frontal dentition, for a radiograph of the front part (roughly from canine to canine);
- Ortho Rad Panoramic which reduces teeth overlap, thereby improving the diagnosis of interproximal decay;
- Bitewing left or right for lateral dentition (generally from eighth to fourth) with a trajectory that reduces teeth overlap;
- Bilateral Bitewing (left and right), which sequentially performs both bitewings, showing them on the same image.

The images are acquired by a CCD sensor and are displayed on a monitor, and image manipulation, archiving and communication are performed via a computer (not included in the device). In particular, Rotograph Prime is equipped with a PAN sensor: it is suitable for Panoramic-type imaging, all Panoramic, i.e. all images with about 14cm-high field; all Panoramic, TMJ, and Sinus images belong to this type. Here below a list of the main characteristics of the digital sensor:

- Detector type: FFT-CCD area image sensor
- Sensible area (HxL) PAN Sensor: 146x6 mm
- Pixel dimension: 48 µm (96 µm in 2X2 binning mode)
- Number of pixels: 3072x128
- Spatial resolution: 4 lp/mm
- Sensor cover attenuation equivalent: <0.4 mm Al eq.

Installation mode

The x-ray system is sold only in a wall mounted version.

Accessories and components

The device can be equipped with different accessories to fulfill different diagnostic needs, such as standard chin support with bite stick, chin support for edentulous patients and X-ray push button with extensible cable.

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
- handles

Chin supports and bite sticks are unchanged from predicate device. Handles and temple support rods are specific for the subject device.
All parts in contact with patient have been assessed according to ISO 10993.
Contact duration is in the range of seconds to few minute and contact type is surface-contacting.

Indication for Use: Rotograph Prime (and I-MAX under trade mark Owandy Radiology) 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.

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

	Villa Sistemi Medicali - Rotograph Prime and Owandy Radiology - I-MAX 510(k) number tbd	**Villa Sistemi Medicali Rotograph EVO D 510(k) number K090749**
Intended Use	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.	Extraoral source x-ray system, 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 (and I-MAX under trade mark Owandy Radiology) has the same functions in the same environment as the predicate device. In particular, the proposed devices perform the same exams for the examination of teeth, jaw and oral structures, as the Rotograph EVO D device.
The proposed devices also use a high frequency x-ray generator with the same x-ray exposure time control and focal spot value of the predicate device.
In the subject devices, patient positioning is assured through two laser pointers that allow to locate the reference planes, as in Rotograph EVO D predicate device.

The subject device detector is exactly the same model as the predicate device detector. The equivalence of the image quality of panoramic radiographies of the subject device vs predicate device has been assessed with image comparison tests.
For all these reasons, Rotograph Prime (and I-MAX under trade mark Owandy Radiology) share the fundamental technological characteristics as the predicate device, even if there are some minor differences, not affecting the safety and effectiveness, between the subject and predicate devices.

The following tables list the similarities and the differences between the subject device (Rotograph Prime under trade mark Villa Sistemi Medicali and I-MAX under trade mark Owandy Radiology) and the predicate device (Rotograph EVO D, manufactured by Villa Sistemi Medicali and cleared by FDA with 510(k) number K090749).

Similarities

	Villa Sistemi Medicali - Rotograph Prime and Owandy Radiology - I-MAX 510(k) number K162190	**Villa Sistemi Medicali Rotograph EVO D 510(k) number K090749**
Versions		
Digital	YES	YES
Exam projections		
Pan	YES	YES
Improved orthogonality dentition	YES	YES
Segmented Pan	YES	YES
Frontal dentition	YES	YES
Low dose panoramic	YES	YES
TMJ	YES	YES
Sinus	YES	YES
Size of pixel (acquired)	96 μm	96 μm
Magnification (PAN)	1,23 constant	1,23 constant
Source to image distance	500 mm	500 mm
Panoramic max image size	equivalent to 15x30 cm film	equivalent to 15x30 cm film

	Villa Sistemi Medicali - Rotograph Prime and Owandy Radiology - I-MAX 510(k) number K162190	**Villa Sistemi Medicali Rotograph EVO D 510(k) number K090749**
Standard PAN image resolution	1536 x 2805 pixels	1536 x 2805 pixels
Dynamic (acquisition)	12 bit	12 bit
Generator / tube		
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
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
User interface		
Real time visualization	YES	YES
PC connection	Ethernet	Ethernet
Installation		
Telescopic column	YES	YES
Power supply voltage	110-120 V, 50/60 Hz	110-120 V, 50/60 Hz

Differences

See the next paragraph "Detailed description of the differences" for additional information and details about each difference between subject and predicate device.

	Villa Sistemi Medicali - Rotograph Prime and Owandy Radiology - I-MAX 510(k) number K162190	**Villa Sistemi Medicali Rotograph EVO D 510(k) number K090749**
Versions		
Analog	NO	YES
Exam projections		
Ceph	NO	YES
Adult PAN scan time	14.4 sec	13.8 sec
Child PAN scan time	13.3 sec	13.8 sec
Generator / tube		
kV Range	60-70 kV step 2kV	60-86 kV step 2kV
mA range	2-7.1 mA	6-10 mA
Total filtration	2.0 mm Al eq	2.5 mm Al eq
Collimator	Fixed	Automatic
Patient positioning		
Height of chin support	975-1635 mm	920-1755 mm
Patient positioning orientation	face to face	lateral with adjustable mirror
User interface		
On board user interface	keyboard and virtual control panel	keyboard and O-LED display
Installation		
Type of installation	wall mount	floor mount
Current rating	7 A	15 A
Weight (wall mount version)	62 kg	157 kg
Dimensions (wall mount version)	1107 x 953 mm	1260 x 1040 mm

Detailed description of the differences

As detailed described on the following paragraphs, all the differences do not affect the safety and effectiveness of the subject devices.

- **Versions**

The Predicate device is available also in analog version (using film-screen combination as image receptor). The subject device is available only in digital version (using the same digital detector as the predicate device). This choice has been driven by the current market and technology trend. Analog extraoral dental units have substantially disappeared from the market in the last 5 years.

- **Exam projections**

Ceph
The predicate device includes, as an option, also cephalometric exams for the examination of the skull. The subject device doesn't include cephalometric exams. The reason is that the device is dedicated to a market segment in which doctors don't need this exam. The fact that this function is not offered has no impact on the performance of the other available projections neither introduces differences vs pan-only version of the predicate device. The subject device is therefore equivalent to the pan-only version of the predicate device.

Adult Pan Scan time
During panoramic exams, the machine has to perform movements according to the selected exam specific trajectory; the exam scan time is the time taken by the machine to complete these movements. The panoramic exam trajectory implemented in the subject device is slightly slower from the one on the predicate device in order to adapt to the small geometric differences between the units; for this reason the scan time is increased of about 4%.

Cihild Pan Scan time
Due the fact that on the subject device the scan time has been slightly increased, it has been implemented a PAN exam specific for children with a reduced scan time.
In fact, the trajectory of child panoramic exam movements is shorter and dedicated to child patients giving a dose reduction vs. the adult exam. This trajectory has been already used on previous Villa panoramic units. It doesn't require different instructions of patient positioning respect to the adult exam.

- **Generator / tube**

kV Range and mA range
The radiological parameters ranges have been optimized for the exam projections (on subject device ceph exams that requires higher dose is not present) and receptor type (on subject device film version that requires higher dose is not present) available on the subject device.

Total filtration
Due to the reduced kV range, the total filtration has been reduced maintaining the compliance with 21CFR 1020.30

Collimator
Due to the absence of the ceph exams, only one collimator slot is needed on the subject device. This collimator slot corresponds to the one of the predicate devices for the exam projections available on the subject device.

- **Patient positioning**

Height of chin support
The Height range of chin support has been reduced based on the following assumption: 975mm correspond to the height of the chin of a 7 years old child, according to the Dreyfuss Tables and 1635mm correspond to the height of the chin of a man of about 190cm of height. According to the Dreyfuss tables this cover about 99% of the adult population.

Patient Positioning orientation
A difference has been introduced in the patient orientation with respect to the machine and operator. In the predicate device, the patient is facing the column; in order for the operator to have visibility of the patient's face, a mirror is present on the column. In the subject device the patient is facing to the left of the equipment, making it possible for the operator to have a direct face-to-face visibility of the patient, therefore improving the positioning accuracy and patient's confidence.

- **User interface**

The user interface of the subject device is made by a keyboard on the machine to drive movements and lasers plus a virtual control panel on PC to select exams and their parameters. The user interface of the predicate device is on board but its digital version has also a virtual control panel on the PC with which exams and their parameters can be selected. The reason of this difference is related to the fact that the subject device, being only digital, always requires a PC so the on board keyboard could be removed while the predicate device needed the on-board keyboard for exam selection for the analog version that doesn't require a PC to work.

- **Installation**

Type of installation
The weight reduction of the subject device respect to the predicate device made it possible to produce a fully wall-mounted version which leaves the floor space free from support structures and more comfortable for the patient, especially in case of particular needs, such as wheelchairs.

Current rating
Due to the different radiological parameters ranges respect to the predicate device, the current rating of the subject device is also reduced

Weight (wall mount version)
Due to the absence of analog version and cephalometric device, and thanks to the use of light-weight materials and optimized components design, the weight of subject device has been significantly reduced compared to the predicate device. The weight reduction doesn't affect the robustness of the device

Dimensions (wall mount version)
Due to the optimized components design, the dimension of subject device has been reduced compared to the predicate device

- **Regarding software**

The elimination of the analog (film) version, the cephalometric option and the automatic collimator contributed to the simplification both of the overall electronic and of the software architecture. The changes to the virtual control panel on PC - to select exams and their parameters - are limited just only to the cosmetic graphics elements. No other significant change is present in the software.

The review of the technological differences between the subject device and the predicate device shows that they are due only to technological evolution and removal of not needed functions and/or version so they do not raise any new questions regarding safety or effectiveness of the Rotograph Prime (and I-MAX under trade mark Owandy Radiology). Basing on the above considerations, we can conclude that the Rotograph Prime (and I-MAX under trade mark Owandy Radiology) is as safe and effective as the predicate device.

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 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" were performed in order to assess the image quality and the relevant analysis has been supplied (see annex 7_Image_Quality_Comparison).

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 (and I-MAX 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. Despite some minor technological differences, Rotograph Prime (and I-MAX under trade mark Owandy Radiology) can be considered as safe and as effective as the predicate device and therefore substantially equivalent to the predicate Rotograph EVO D.