December 28, 2023

de Götzen S.r.l.
Fabio Lissandrello
Quality Assurance and Regulatory Affairs Manager
Strada Provinciale Busto-Cassano 3
Fagnano Olona, Varese 21054
Italy

Re: K231055
Trade/Device Name: x-mind dc (under trademark Acteon), Owandy-RX DC (under trademark OwandyRadiology)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: November 29, 2023
Received: November 29, 2023

Dear Fabio Lissandrello:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gabriela M. Rodal -S Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231055

Device Name
x-mind dc (under trademark Acteon)
Owandy-RX DC (under trademark Owandy Radiology)

Indications for Use *(Describe)*
x-mind dc (and Owandy-RX DC under trademark Owandy Radiology) is an X-ray unit, in particular extraoral source of X-rays, intended for intra-oral radiographic exams for diagnostic purposes related to anatomy of teeth and adjacent oral structures both on adult and pediatric patients, using specific x-ray detectors (chemical films, phosphor plates or digital x-ray sensors) that are not part of the device.
The device is operated and used by dentists, radiologists and other legally qualified health care professionals.

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

Name	de Götzen S.r.l.
Address	Strada Provinciale Busto-Cassano 3, 21054 Fagnano Olona (VA), Italy
Telephone	+39 0331 376760
Contact Person	Fabio Lissandrello – fabio.lissandrello@acteongroup.com
Date Prepared	November 29th, 2023

II. PROPOSED DEVICE

Name of Device	x-mind dc (under trademark Acteon) Owandy-RX DC (under trademark Owandy Radiology)
Common or Usual Name	Unit, x-ray, extraoral with timer
Classification Name	Extraoral source X-ray system
Regulation Number	21 CFR 872.1800
Product Code	EHD
Regulatory Class	II

III. PREDICATE DEVICE AND REFERENCE DEVICE

PREDICATE DEVICE	
510(k) Number	K130109
Clearance date	August 1st, 2013
Device Name	Endograph DC
Applicant	Villa Sistemi Medicali S.p.A.
Classification Name	Extraoral source X-ray system
Regulation Number	21 CFR 872.1800
Product Code	EHD
Regulatory Class	II

REFERENCE DEVICE	
510(k) Number	K042260
Clearance date	September 7th, 2004
Device Name	PHOT-X II, MODEL 303
Applicant	Takara Belmont USA, Inc.
Classification Name	Extraoral source X-ray system

Regulation Number	21 CFR 872.1800
Product Code	EHD
Regulatory Class	II

IV. DEVICE DESCRIPTION

NOTE: In the following, all the references to x-mind dc are applicable also to Owandy-RX DC under trademark Owandy Radiology.

x-mind dc consists of the following parts:

1 - X-ray control unit (timer)
2 - Wall plate and horizontal bracket
3 - Pantograph type arm (scissor arm)
4 - X-ray source assembly (tubehead)
5 - Collimator cone (Beam Limiting Device)

The timer is the control panel used to manage the exposure settings and to safely use the tubehead. It allows easy and clear selection, with the help of clear and visible signals, of the exposure settings, perform personal settings and display alarms of the device in case of incorrect operation or eventual failures.
The horizontal bracket it is available in 3 different lengths and represents the support for the scissor arm.
The pantograph arm, being adjustable in height and depth, allows the precise positioning of the tubehead.
The tubehead of the device contains the X-ray tube, the high voltage board and the high frequency generator. It is the component of the device which emits the X-rays.
The collimator cone represents the part of the device in contact with the patient and it allows the correct focal spot to skin distance, ensures the dimension, direction and centering of the X-ray beam.
x-mind dc can be used with conventional chemical films (D, E, F speed films), phosphor plates (PSP), RVG digital detectors (CCD or CMOS).

V. INDICATIONS FOR USE

x-mind dc (and Owandy-RX DC under trademark Owandy Radiology) is an X-ray unit, in particular extraoral source of X-rays, intended for intra-oral radiographic exams for diagnostic purposes related to anatomy of teeth and adjacent oral structures both on adult and pediatric patients, using specific x-ray detectors (chemical films, phosphor plates or digital x-ray sensors) that are not part of the device.
The device is operated and used by dentists, radiologists and other legally qualified health care professionals.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

NOTE: In the following, all the references to x-mind dc are applicable also to Owandy-RX DC under trademark Owandy Radiology.

Description	Subject Device	Predicate Device	Comparison
Name	x-mind dc	Endograph DC	N/A
Manufacturer	de Götzen S.r.l.	Villa Sistemi Medicali S.p.A.	N/A
510(k) number	TBD	K130109	N/A
Intended Use / Indications for Use	x-mind dc is an X-ray unit, in particular extraoral source of X-rays, intended for intra-oral radiographic exams for diagnostic purposes related to anatomy of teeth and adjacent oral structures both on adult and pediatric patients, using specific x-ray detectors (chemical films, phosphor plates or digital x-ray sensors) that are not part of the device. The device is operated and used by dentists, radiologists and other legally qualified health care professionals.	Endograph DC is an extraoral source x-ray unit for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The device is to be operated and used by dentists, radiologists and other legally qualified health care professionals. It can be used with both pediatric and adult patients.	Equivalent

Device technical data			
Type of power supply	Single phase alternate	Single phase alternate	Same
Nominal voltage	230 V 115 V	110 ÷ 240 V	Different
Line voltage regulation	≤ 3%	≤ 3%	Same
Maximum voltage variation	±10%	±10%	Same
Nominal current	5,2 A @ 230 V 9,5 A @ 115 V	2,4 A @ 240 V 5,4 A @ 110 V	Different
Frequency	50/60 Hz	50/60 Hz	Same
Adsorbed power	1,2 kVA @ 230 V 1,1 kVA @ 115 V	570 VA @ 240 V 582 VA @ 110 V	Different
Max. apparent line resistance	0,5 Ω @ 230 V 0,2 Ω @ 115 V	0,8 Ω (181-264 V) 0,4 Ω (99-180 V)	Different
Protection against electrical shock (insulation class)	Class I	Class I	Same
Degree of protection against electrical shock (applied part)	Type B	Type B	Same
Generator type	High frequency, constant potential (DC)	High frequency, constant potential (DC)	Same
Nominal anode voltage	60 / 70 kV	60 / 65 / 70 kV	Similar
Nominal anode current	4 / 8 mA	6 mA	Different
Exposure time	0,020 s ÷ 3,2 s (23 steps)	0,01 s ÷ 2,0 s (36 steps)	Different
Focal spot size	0,7 mm	0,4 mm	Different
Anode material	Tungsten	Tungsten	Same
Total filtration at 70 kV	2,4 mm Al	≥ 2,5 mm Al	Similar
Half value layer (HVL) at 70 kV	2,2 mm Al	> 2 mm Al	Similar
Leakage radiation	< 0,25 mGy/h	< 0,25 mGy/h	Same
Focal length (SSD)	20 cm (short cone) 31 cm (long cone, rectangular cone)	20 cm 30 cm with optional collimator cone	Similar

X-ray exposure button	Cabled or wireless exposure switch	Cabled or wireless exposure switch	Same
Exposure modes	Preset loading factors or manual mode	Preset loading factors or manual mode	Same
Image receptor type	Film, phosphor plate, digital sensor	Film, phosphor plate, digital sensor	Same
Patient type	Adult and child	Adult and child	Same
Installation	Wall mount Mobile Chair Ceiling	Wall mount Mobile	Similar (more installation option for the subject device)

Both the subject and predicate device are X-ray equipment for dental intra-oral X-ray imaging, particularly they are extra-oral sources of X-rays intended to be used for producing diagnostic X-ray images of the teeth and adjacent oral structures.
Both devices are intended to be used by dentists, radiologists and other legally qualified health care professionals, and can be used both on adult and pediatric patients.
The type of X-ray detectors used for producing the X-ray images is clearly stated in the intended used of the subject device, the same kind of detectors is used also with the predicate device to obtain the radiographic exams.
Although worded differently, there are no differences between the subject device and the predicate device with respect to indications and intended use.

The subject and the predicate device are intra-oral X-ray units which use a high frequency constant potential (DC) generator for producing the X-rays, and some differences exist under the electrical data characteristics. These differences are just due to the different design specifications of the power supply board, which do not raise issue of safety and effectiveness. Both devices have been tested with the same performance testing and comply with the general requirements for basic safety and essential performance of medical electrical equipment and dental intra-oral X-ray equipment and have the same classification for the protection against the electrical shock.
The differences related to the tubehead characteristics are due to the different design specifications of the X-ray generation system, however both devices conform to the same safety and performance standards.

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

VII. PERFORMANCE DATA

The performance of the subject device and the predicate device have been validated using the same or updated versions of the testing methods.

Applied standards		
Subject Device: x-mind dc	**Predicate Device: Endograph DC**	**Comparison**
IEC 60601-1:2005 + AMD1:2012	IEC 60601 1: 2005 + Corr.1 (2006) + Corr.2 (2007)	Updated version
IEC 60601-1-2:2014	IEC 60601-1-2:2014	Same
IEC TR 60601-4-2:2016	-	
IEC 60601-1-3:2008 + AMD1:2013	IEC 60601-1-3:2008	Updated version
IEC 60601-1-6:2010 + AMD1:2013	IEC 60601-1-6:2010	Updated version
IEC 60601-2-65:2012 + AMD1:2017	IEC 60601-2-65:2012	Updated version
IEC 62304:2006 + AMD1:2015	IEC 62304:2006 + Ac:2008	Updated version
IEC 62366-1:2015 + AMD1:2020	IEC 62366:2007	Updated version
ANSI/AAMI ES60601-1:2012	ANSI/AAMI ES60601-1:2005	Updated version
CAN/CSA-C22.2 N. 60601-1:14	CAN/CSA-C22.2 No 60601-1:08	Updated version
ETSI EN 300 220-2 v.3.2.1	ETSI EN 300 220-2 v.3.1.1	Updated version
ETSI EN 301 489-3 v.2.1.2	ETSI EN 301 489-3 v.1.6.1 and Final Draft ETSI EN 301 489-3 v.2.1.1	Same
CFR Title 47 Part 15 Subpart C – Intentional Radiators 15.231	CFR Title 47 Part 15 Subpart C – Intentional Radiators 15.231	Same
ISO 10993-1:2018	ISO 10993-1:2009	Updated version

The following performance data were provided in support of the substantial equivalence determination.
Non-Clinical test performed on the subject device:

1) Electrical Safety, Electromagnetic Compatibility (EMC) and Performance
The device complies with:

- IEC 60601-1:2005 + AMD1:2012
- IEC 60601-1-2:2014
- IEC TR 60601-4-2:2016
- IEC 60601-1-3:2008 + AMD1:2013
- IEC 60601-1-6:2010 + AMD1:2013
- IEC 60601-2-65:2012 + AMD1:2017
- IEC 62366-1:2015 + AMD1:2020
- ANSI/AAMI ES60601-1:2012
- CAN/CSA-C22.2 N. 60601-1:14
- ETSI EN 300 220-2 v.3.2.1
- ETSI EN 301 489-3 v.2.1.2
- CFR Title 47 Part 15 Subpart C – Intentional Radiators 15.231
- 21 CFR §1020.30 Diagnostic x-ray systems and their major components.
- 21 CFR §1020.31 Radiographic equipment

2) Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a Moderate Level of Concern. The software complies with IEC 62304:2006+AMD1:2015.

3) Biocompatibility testing
The biocompatibility evaluation for x-mind dc was conducted in accordance with ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process.

In addition to this, the tubehead characteristics of the subject device are compared with the ones of a legally marketed reference device:

Device technical data	**Subject Device x-mind dc**	**Reference Device Phot-X II Model 303**	**Comparison**
Generator type	High frequency, constant potential (DC)	High frequency, constant potential (DC)	Same
Nominal anode voltage	60 / 70 kV	60 / 70 kV	Same
Nominal anode current	4 / 8 mA	4 / 7 mA	Similar
Exposure time	0,02 s ÷ 3,2 s (23 steps)	0,01 s ÷ 3,2 s (23 steps)	Similar
Anode material	Tungsten	Tungsten	Same
Focal spot size	0,7 mm	0,7 mm	Same

Both the subject and the reference devices use a tubehead with the same technology, based on a high frequency constant potential (DC) generator for producing the X-rays. The design characteristics of the tubeheads are equivalent, as well as the selectable exposure time range is basically the same. Also, the X-ray tubes have the same anode material and same focal spot size.
This comparison supports the tubehead performance data of the subject device, which is as safe and effective as the legally marketed reference device.

Bench testing was performed to characterize device performance and resultant image quality when device is used/integrated with cleared x-ray receptor(s) meeting recommended specifications. Sample clinical images, evaluated by a clinical expert, demonstrated diagnostic quality output when device is integrated with recommended cleared x-ray receptor(s). The performance was demonstrated to be substantially equivalent to the predicate.

VIII. FDA GUIDANCE DOCUMENTS

The following FDA guidance documents have been used for the preparation of this 510(k) submission:

- Format for Traditional and Abbreviated 510(k)s, dated September 13, 2019
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)], dated July 28, 2014
- Pediatric Information for X-ray Imaging Device Premarket Notifications, dated November 28, 2017

- Radio Frequency Wireless Technology in Medical Devices, dated August 14, 2013
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", dated September 4, 2020
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, dated May 11, 2005
- Electromagnetic Compatibility (EMC) of Medical Devices, dated June 6, 2022

IX. CONCLUSION

x-mind dc has the same indication for use as the predicate device. It performs the same functions in the same environment as the predicate device. It is based on a well-known technology for the X-ray generation. It shares the same main technological characteristics as the predicate device. Minor technological differences do not raise any new questions regarding safety or effectiveness of the device, so it is as safe and effective as the predicate device.