



Food and Drug Administration
10903 New Hampshire Avenue
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Digimed Co., Ltd. (Digimed Corporation until Dec. 31, 2012)
% Mr. Yong Park
President
Innoden LLC.
212 Wells Avenue, S# 102
RENTON WA 98057

December 3, 2015

Re: K152859
Trade/Device Name: Portable X-ray System (Model: MINIX-V / MINIX-S)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: September 30, 2015
Received: September 30, 2015

Dear Mr. Park:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a grey shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152859

Device Name

Portable X-ray System (Models: MINIX-V, MINIX-S)

Indications for Use (Describe)

The device is a diagnostic X-ray system, which is intended to be used by trained dentists and dental technicians as an extra-oral X-ray source for producing diagnostic X-ray images using intra-oral image receptors. Its use is intended for both adults and pediatric subjects.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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510(k) Summary of Portable X-ray System (MINIX-V&MINIX-S)

1. Company and Correspondent Making the Submission:

Date Prepared:	Sep. 16, 2015
Company Name:	DIGIMED CO., LTD. (DIGIMED CORPORATION. until Dec. 31, 2012)
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Contact:	Youngbae Kwon, Managing Director

2. US Agent for FDA Contact:

Name	Mr. Yong Park
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Telephone number:	425-572-0283
Fax:	425-988-1256
E-mail:	drpark@innoden.com

3. Device Information:

Proprietary-Trade Name:	Portable X-Ray System (Models: MINIX-V, MINIX-S)
Classification Name:	Extra-oral Source X-Ray System: EHD, Class II per regulation 21CFR 872.1800
Common/Usual Name:	Portable X-Ray System

4. Predicate Devices:

Manufacturer:	GENORAY	DIGIMED
Device:	Portable X-Ray System (Model: PORT-X II)	Portable X-Ray System (Model: BIOX, PROX/DIOX-602)
Classification:	Extra-oral Source X-Ray System: EHD, Class II per regulation 21CFR 872.1800	Extra-oral Source X-Ray System: EHD, Class II per regulation 21CFR 872.1800
510(k) Number:	K063121 (Decision Date: Jan. 11, 2007)	K103600 - BIOX (Decision Date: Mar. 10, 2011) K082167 - PROX / DIOX-602 (Decision Date: July 29, 2008)

5. Indications for Use (Intended Use):

The Portable X-ray System (Models: MINIX-V, MINIX-S) is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors. Its use is intended for both adult and pediatric subjects.

Compatible intra-oral image receptors are described as below.

- 1) Analog dental x-ray films
- 2) CCD and CMOS digital sensors
- 3) Digital phosphor plates
- 4) Most of the intra-oral image receptors which intended for dental x-ray examination

6. Description of Device

The portable x-ray system (Models: MINIX-V, MINIX-S) is an x-ray generating device which is mainly designed for dental examination (teeth and jaw).

Operating principle is that the high voltage electricity is getting into x-ray tube and generates x-ray source. This x-ray source comes out from the emitting cone and penetrates teeth and jaw, and makes x-ray images through image receptors (chemical film or digital sensor). Once the power is supplied from the rechargeable lithium-ion polymer battery pack, the inverter generates high frequency and high voltage. Boosted and rectified DC high voltage (MINIX-V: 70kV, MINIX-S: 60kV) is loaded onto the x-ray tube, and the tube generates x-ray.

Micro control unit (MCU) and other control parts function to display data on LCD and control the system by the input information from user interface. When operator controlled (fixed amount of) x-ray is exposed to patient's teeth and jaw, clinician can examine the parts with processed images from intra-oral image receptors (analog film, digital phosphor plate or digital sensor).

The Portable X-ray System (Models: MINIX-V, MINIX-S) is composed of an x-ray generating part with an x-ray tube, a device controller (Control PCB), a power controller (Power PCB), an user interface (LCD window), a beam limiting part (x-ray emitting cone), a backscatter shield, and a remote control switch (hand-switch).

The Portable X-ray System (Models: MINIX-V, MINIX-S) is a diagnostic x-ray system, which is intended to be used by trained dentists or dental technicians. Its use is intended for both adult and pediatric subjects. This device includes a high frequency inverter that changes direct current to alternating current, x-ray tube, electrical protective devices, and other elements. The system with high frequency x-ray provides sharp and clear images, and the total lead protection seal protects patients and dentists from leakage or scattered radiation from the device.

7. Safety and Effectiveness, Comparison to Predicate Device:

Safety and effectiveness of the subject device is considered with the latest version of test regulations. The subject device was shown to provide an equivalent level of safety and performance as compared to the predicate devices.

“Clinical images were provided however they were not necessary in order to establish substantial equivalence with the predicate devices”

8. Safety, EMC and Performance Data:

The subject device complies with the safety and performance standards listed in the chart below. Test reports were provided to demonstrate conformance. All required documents and reports are submitted to the appropriate oversight agency to establish compliance with the applicable requirements.

9. The differences between the subject device and the predicate devices

The subject device has little differences with its design, size, and user interface compare to the predicate devices. Detailed differences can be identified from “Substantial Equivalence Chart”.

10. Substantial Equivalence Chart

1) Predicate device (Model: **PORT-X II**) from **GENORAY**

FEATURE	GENORAY PORT-X II (K063121)	DIGIMED MINIX-V (NEW)	DIGIMED MINIX-S (NEW)
<u>INTENDED USE</u>	All three systems are intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.		
<u>MECHANICAL</u>			
Size	7.8" x 5.8" x 3.7"	4.8" x 8.7" x 5.3"	4.8" x 8.7" x 5.3"
Source to skin distance	10 cm	20 cm	20 cm
Cone diameter	7 cm	5.5 cm	5.5 cm
User interface	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size and tooth selection icons on an LCD display	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display
Backscatter radiation protection	None	6.3" dia. Pb-filled acrylic plastic scatter shield	6.3" dia. Pb-filled acrylic plastic scatter shield
Exposure switch	Exposure button at x-ray control panel	Exposure button at front cover on right hand side, or a remote control switch	Exposure button at front cover on right hand side, or a remote control switch
Tubehead mounting	Handheld, or on a tripod	Handheld, on optional arms or on a tripod	Handheld, on optional arms or on a tripod
Half-value layer	(not available)	2.3 mm Al	2.0 mm Al
<u>ELECTRICAL</u>			
Energy source	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack
Exposure time	0.01~2.0 seconds in 46 steps	0.01~2.0 seconds in 0.01 increments	0.01~2.0 seconds in 0.01 increments
Time Accuracy	± (10% +1 ms)	± (10% +1 ms)	± (10% +1 ms)
mA	2 mA fixed	2 mA fixed	2 mA fixed
kVp	60 kV fixed	70 kV fixed	60 kV fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)	Constant Potential (DC)
Duty Cycle	(not available)	1:60	1:60
EMI standards	EN60601-1-2	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3
<u>X-RAY PERFORMANCE</u>			
Performance standards	EN 60601-1 EN 60601-1-3 EN 60601-2-7 EN 60601-2-28 EN 60601-2-32	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65
Difference	SSD, Cone diameter, Backscatter radiation protection, Exposure switch, kV (MiniX-V only)		

2) Predicate device (Model: **PROX/DIOX-602**) from **DIGIMED**

FEATURE	DIGIMED PROX/DIOX-602 (K082167)	DIGIMED MINIX-V (NEW)	DIGIMED MINIX-S (NEW)
<u>INTENDED USE</u>	All three systems are intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.		
<u>MECHANICAL</u>			
Size	PROX: 7" x 9.3" x 5.4" DIOX-602: 5.3" x 9.4" x 6.9"	4.8" x 8.7" x 5.3"	4.8" x 8.7" x 5.3"
Source to skin distance	20 cm	20 cm	20 cm
Cone diameter	6 cm	5.5 cm	5.5 cm
User interface	Up-down buttons for exposure time selection with timer display. Anatomical tooth buttons, patient size change button, and image receptor type change button. Each button shows icons on an LCD display. Several user-selectable preset times.	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display
Backscatter radiation protection	6.3" dia. Pb-filled acrylic plastic scatter shield	6.3" dia. Pb-filled acrylic plastic scatter shield	6.3" dia. Pb-filled acrylic plastic scatter shield
Exposure switch	Exposure button at front cover on right hand side, or a remote control switch	Exposure button at front cover on right hand side, or a remote control switch	Exposure button at front cover on right hand side, or a remote control switch
Tubehead mounting	Handheld, on optional arms or on a tripod	Handheld, on optional arms or on a tripod	Handheld, on optional arms or on a tripod
Half-value layer	2.0 mm Al	2.3 mm Al	2.0 mm Al
<u>ELECTRICAL</u>			
Energy source	Rechargeable 24 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack
Exposure time	0.01~1.6 seconds in 0.01 increments	0.01~2.0 seconds in 0.01 increments	0.01~2.0 seconds in 0.01 increments
Time Accuracy	± (10% +1 ms)	± (10% +1 ms)	± (10% +1 ms)
mA	2 mA fixed	2 mA fixed	2 mA fixed
kVp	60 kV fixed	70 kV fixed	60 kV fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)	Constant Potential (DC)
Duty Cycle	1:60	1:60	1:60
EMI standards	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3
<u>X-RAY PERFORMANCE</u>			
Performance standards	EN 60601-1 EN 60601-1-3 EN 60601-2-7 EN 60601-2-28 EN 60601-2-32	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65
Difference	Cone diameter, Energy source, Exposure time, kV (MiniX-V only)		

3) Predicate device (Model: **BIOX**) from **DIGIMED**

FEATURE	DIGIMED BIOX (K103600)	DIGIMED MINIX-V (NEW)	DIGIMED MINIX-S (NEW)
<u>INTENDED USE</u>	All three systems are intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.		
<u>MECHANICAL</u>			
Size	7.6" x 9.3" x 5.4"	4.8" x 8.7" x 5.3"	4.8" x 8.7" x 5.3"
Source to skin distance	21 cm	20 cm	20 cm
Cone diameter	6 cm	5.5 cm	5.5 cm
User interface	Up-down buttons for exposure time selection with timer display. Anatomical tooth buttons, patient size change button, and image receptor type change button. Each button shows icons on an LCD display. Several user-selectable preset times.	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size, image-receptor type, and tooth selection icons on an LCD display
Backscatter radiation protection	6.3" dia. Pb-filled acrylic plastic scatter shield	6.3" dia. Pb-filled acrylic plastic scatter shield	6.3" dia. Pb-filled acrylic plastic scatter shield
Exposure switch	Exposure button at front cover on right hand side, or a remote control switch	Exposure button at front cover on right hand side, or a remote control switch	Exposure button at front cover on right hand side, or a remote control switch
Tubehead mounting	Handheld, on optional arms or on a tripod	Handheld, on optional arms or on a tripod	Handheld, on optional arms or on a tripod
Half-value layer	2.0 mm Al	2.3 mm Al	2.0 mm Al
<u>ELECTRICAL</u>			
Energy source	Rechargeable 24 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack
Exposure time	0.01~1.6 seconds in 0.01 increments	0.01~2.0 seconds in 0.01 increments	0.01~2.0 seconds in 0.01 increments
Time Accuracy	± (10% +1 ms)	± (10% +1 ms)	± (10% +1 ms)
mA	3 mA fixed	2 mA fixed	2 mA fixed
kVp	60 kV fixed	70 kV fixed	60 kV fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)	Constant Potential (DC)
Duty Cycle	1:60	1:60	1:60
EMI standards	EN60601-1-2, IEC60601-1-2 CISPR 11, EN61000-3-2, EN61000-3-3	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3
<u>X-RAY PERFORMANCE</u>			
Performance standards	EN 60601-1 EN 60601-1-3 EN 60601-2-7 EN 60601-2-28 EN 60601-2-32	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65
Difference	SSD, Cone diameter, Energy source, Exposure time, mA (BIOX), kV (MiniX-V only)		

11. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided above comparison table, the Portable X-ray System (Models: MINIX-V, MINIX-S) has little difference with its size and user interface as the information in the table. But the system is substantially equivalent to the predicate devices with its design, mechanical and electrical performance as described.

Performance evaluation (test) reports and device inspection report confirmed that the Portable X-ray System (Model: MINIX-V, MINIX-S) is suitable for its intended use and user instruction of the device.