August 10, 2018

DIGIMED Co., Ltd.
% Mr. Yong Park
President
INNODEN LLC
212 Wells Ave.S #102
RENTON WA 98057

Re: K181891
Trade/Device Name: Portable X-ray System (Models: MiniX-V, MiniX-S)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: July 13, 2018
Received: July 13, 2018

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. 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); and Part 809; 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,

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)*

K181891

Device Name
Portable x-ray system (Model: 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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:	**Mar. 12, 2018**
Company Name:	**DIGIMED CO., LTD.**
Address:	309~311, 318-ho, 145, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08506 Rep. of Korea
Telephone number:	+82-2-2624-1551
Fax:	+82-2-2624-1553
E-mail:	digimed@digimed.co.kr
Contact:	Youngbae Kwon, CEO

2. US Agent for FDA Contact:

Name	Mr. Yong Park
Company Name:	**INNODEN LLC.**
Address:	212 Wells Ave. S #102, Renton, WA 98057
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:	**DIGIMED CO., LTD.**
Device:	Portable X-Ray System (Model: **MiniX-V, MiniX-S**)
Classification:	Extra-oral Source X-Ray System: **EHD**, **Class II** per regulation 21CFR 872.1800
510(k) Number:	**K152859**

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.

The device has an x-ray tube for generating x-rays, a high voltage transformer for generating high voltages, a high voltage rectification circuit for transforming and boosting AC voltage to mixed pulse voltage, a high voltage divide circuit for lowering high voltage to low voltage to measure and calibrate high voltages, as well as a high voltage tube tank, a high frequency inverter circuit for generating high voltages, a control P.C.B for controlling, saving and displaying the data, a power P.C.B for supplying power to the circuit and apparatus in housing, user interface (LCD screen) and beam limiting part (x-ray emitting cone).

The apparatuses above can be embedded in one or several cases, and except for the radiation opening in the x-ray system, all units are completely shielded by lead or high-density materials, protecting patients and users from unnecessary exposure of radiation.

The package includes a remote control switch, a battery charger, and a backscatter shield. And the remote control switch can be used when the device is mounted on fixable stands as optional arms in user manual or digital camera tripods.

Operating principle is that the high voltage electricity is getting into the x-ray tube and generates x-ray source. This x-ray source comes out from the emitting cone and goes through teeth and jaw of patient, and makes x-ray images onto image receptors as a chemical film or a digital sensor.

Once the user enters the desired tube voltage data in the numerical value (%) by means of the user interface and press the x-ray exposure button, the system generates mixed pulse voltage (**MiniX-V**: 70kV max, **MiniX-S**: 60kV max) from the transformed and boosted AC voltage through high voltage generator. So the user is able to obtain x-ray images of patients' teeth and jaws from the image receptors, and diagnose about the images.

Detailed information of the device is described in "**13. Device Description**" of this submission.

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. FDA Guidance Documents utilized;

1) Radiation Safety Considerations for X-ray Equipment Designed for Hand-Held Use, issued December 24, 2008
2) Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005
3) Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 28, 2017
4) Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued October 2, 2014

11. Substantial Equivalence Chart

1) Predicate device (Model: **MiniX-V, MiniX-S**) from **DIGIMED**

FEATURE	DIGIMED **MiniX-V, MiniX-S** (**K152859**)	DIGIMED **MiniX-V, MiniX-S** (**K181891**)
INTENDED USE	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.	
MECHANICAL		
Size	4.8" x 8.7" x 5.3"	4.8" x 8.7" x 5.3"
Source to skin distance	20 cm	20 cm
Cone diameter	5.3 cm	5.3 cm
User interface	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
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
Tubehead mounting	Handheld, on optional arms or on a tripod	Handheld, on optional arms or on a tripod
Half-value layer	MiniX-V: 2.3 mm Al MiniX-S: 2.0 mm Al	MiniX-V: 2.3 mm Al MiniX-S: 2.0 mm Al
ELECTRICAL		
Energy source	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 0.01 increments	0.01~2.0 seconds in 0.01 increments
Time Accuracy	± (10% +1 ms)	± (10% +1 ms)
mA	2 mA fixed	2 mA fixed
kVp	MiniX-V: 70kV MiniX-S: 60kV	70 kV max
Waveform	Constant Potential (DC)	**Mixed pulse**
Duty Cycle	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
X-RAY PERFORMANCE		
Performance standards	IEC 60601-1 IEC 60601-1-3 IEC 60601-2-65	IEC 60601-1 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304
Difference	**X-ray waveform**	

12. 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 new 510k submission of the portable x-ray system (Models: MiniX-V, MiniX-S) has difference with its x-ray waveform compare to previous submission (K152829). Except the waveform, the system has the same specification as the previous submission.

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