Denterprise International, Inc.
% Ms. Joyce St. Germain
Regulatory Dept. Manager
510k FDA Consulting / Denterprise International, Inc.
100 E. Granada Blvd., Suite 219
ORMOND BEACH FL 32176

April 4, 2018

Re: K180561
Trade/Device Name: MobileX Portable X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: February 28, 2018
Received: March 5, 2018

Dear Ms. Germain:

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 and Part 809); 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.

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.

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 Diagnostic
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)*
K180561

Device Name
MobileX Portable X-ray System

Indications for Use *(Describe)*
The MobileX Portable X-ray System 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 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.

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510k FDA Consulting

Medical Device Clearances

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510(k) Summary

Submitter/Applicant

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Date Prepared: February 28, 2018

Preparer/Consultant

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Secondary Contacts: Claude Berthoin, CEO (claude@denterpriseintl.com).

Device Classification

Trade/Model Names:	MobileX Portable X-ray System / (T-100)
Common Name:	Portable X-ray System
Regulation Name:	Extra-oral Source X-ray System
Regulation Number:	21 CFR 872.1800
Primary Product Code:	EHD
Classification Name:	Unit, X-ray, Extraoral with Timer
Regulatory Class:	II
510k Review Panel:	Dental

Predicate Device

The subject device claims equivalence to the following legally marketed predicate:

510(k) Number:	K152859
Applicant:	Digimed Co., Ltd., Korea
Date Cleared:	December 3, 2015
Trade Name:	Portable X-ray System (Model: MiniX-V)
Regulation Name:	Extra-oral Source X-ray System
Regulation Number:	21 CFR 872.1800
Primary Product Code:	EHD
Classification Name:	Unit, X-ray, Extraoral with Timer
Regulatory Class:	II
510k Review Panel:	Dental

Indications for Use

MobileX 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 receptors. Its use is intended for both adults and pediatric subjects.

Intended Use

Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.

Device Description

MobileX Portable X-ray System of Denterprise International, Inc., is a handheld x-ray device. The technology of this device was originally developed in Korea more than a decade ago and global production is still concentrated in that country.

The subject device is designed for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structure by exposing an x-ray image receptor to ionizing radiation. The x-ray source, a tube, is located inside the handheld device. All three conventional types of intraoral receptors can be used with this device—analog x-ray film, digital phosphorous plates, and digital x-ray sensors.

This device is used in general dentistry and is supplied with an internal timer to control the duration of the x-ray source to the patient.

The software is designed for a button operated device to be used by a user and a display window to be observed by the user. The software is for controlling the operation of the hardware according to the user operation that is required for this device. This software is new but this type of software is common for use in the handheld x-ray systems.

Comparison of Technological Characteristics with Predicate

The following table compares technological and other characteristics of the subject and predicate device.

Note: This device has software with a Moderate Level of Concern.

Table 5.1 -- Technological Comparison
Subject Model: T-100

	Subject Device	Predicate Device	Comparison
Device	**Mobile-X Portable X-ray System**	**Portable X-ray System: Model MiniX-V**	**NA**
510(k) Owner	Denterprise International, Inc. (USA)	Digimed Co., Ltd. (Korea)	NA
Classification & Product Code	872.1800; EHD	872.1800; EHD	Same
Intended Use	Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	Intended as extraoral x-ray sources to be used with intraoral image receptors for diagnostic imaging by dentists or dental technicians.	Same
Indication for Use	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 receptors. Its use is intended for	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 receptors. Its use is intended for	Same

	both adults and pediatric subjects.	both adults and pediatric subjects.	
Size	6.5” x 6.0” x 10.5”	4.8” x 8.7” x 5.3”	**Difference of design shape/size**
Source to Skin	20.5 cm	20 cm	**Difference/ Subject Device .5cm farther from patient**
Cone diameter	6.0cm	5.5 cm	**Difference .5cm**
User interface	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable present 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 present times with patient size, image-receptor type, and tooth selection icons on an LCD display	Same
Backscatter radiation protection	153mm (6.02”) dia. 12mm thick pb-filled acrylic plastic scatter shield	6.3” dia. 12mm thick pb-filled acrylic plastic scatter shield	**Slight mm Difference**
Exposure switch	Exposure button at front cover on right hand side.	Exposure button at front cover on right hand side.	Same
Tube-head mounting	Handheld, on optional arms or on a tripod	Handheld, on optional arms or on a tripod	Same
Electrical Information			
Energy source	Rechargeable 11.1V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Polymer battery pack	Same

Exposure time	0.01 ~ 1.3 seconds in 0.01 or 0.05 increments	0.01 ~ 2.0 seconds in 0.01 increments	**Difference**
Time accuracy	± (10% +1 ms)	± (10% +1 ms)	Same
mA	2mA fixed	2mA fixed	Same
kVp	70kVp fixed	70kVp fixed	Same
Waveform	Constant Potential (DC)	Constant Potential (DC)	Same
Duty Cycle	1:60	1:60	Same
Performance standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304 IEC 62366 IEC 6100-3-2 IEC 6100-3-3 ISO 14971	IEC 60601-1 IEC 60601-1-2 CISPR 11 IEC61000-3-2 IEC610003-3 IEC 60601-1-3 IEC 60601-2-65	**Different/Subject Device has additional test**

The above comparison shows the subject and predicate devices have substantially similar technological characteristics. Differences show up in the shape, size, design of the device and those are in cm and mm measurements of slight difference. The exposure time is slightly less with the subject device matched to the predicate. The differences of the device are minor and do not raise new issues of safety and effectiveness.

Non-Clinical Performance Data

The following performance was completed on the subject device in support of the substantial equivalence determination of the predicate device. Clinical data was not needed to support substantial equivalence.

- Electrical Safety and EMC
- Software Validation
- Biocompatibility
- Usability
- Clinical Comparison
- Risk Assessment /Radiation Leakage

- All tests were performed in accordance with ISO standards and tests are recognized by FDA.

- None of the standards were adapted for application to the device under review.

- There were no requirements of any standard that were not applicable to the device.

- No deviations from the standards were applied.

- No differences exist between the tested device and the device to be marketed.

- Test of leakage radiation according to EN 60601-1-3:2010, sub-clause 12.2, 12.4 and IEC 60601-2-65, sub-clause 203.12.2, 203.12.3, 203.12.4. Also tested leakage radiation according to EN 60601-1-3:2010, sub-clause 13.4. The device passed and test methods were verified according to these ISO standards.

- Conformity with all standards was determined by the device manufacturer, Remedi Co., Ltd., Korea.

- Electrical test performed by KCTL, Inc. Laboratories, Inc., Korea.

Specific Guidance Document

There are two FDA Specific Guidance Documents associated with the device: *Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use.* This submission utilized this guidance to develop this device to ensure the safety of this device for both the operators and the patients. The Guidance document: *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* also applies to this device. Details of this guidance are provided within the Software Validation Report.

Labels

The labels on the device show that this device conforms to the following:

21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products,
21 CFR 1020.30: Diagnostic x-ray systems and their major components,

21 CFR 1020.31: Radiographic Equipment

Substantial Equivalence

The above comparison chart shows the subject and predicate devices are substantially equivalent in technological characteristics.

Both devices have:

- The same function and used in the same environment.
- The same indications for use and the same intended use.
- The same manufacturing process and technological characteristics.
- Both devices have completed the ISO standardized testing and have passed and the tests are in the comparison chart shown above.

Conclusion

The subject and predicate device have the same indications for use, the same intended use and have similar technological characteristics. The **MobileX Portable X-ray System** performs the same identical functions, in the same environment as the predicate device. **MobileX** uses the same technology as the predicate device, based on well-known technology. **MobileX** is as safe and effective as the predicate device. We believe the subject device does not introduce any new safety concerns and is substantially equivalent to the predicate device. **In conclusion, the subject device, MobileX Portable X-ray System, is at least as safe and effective as the predicate device and warrants a finding of substantial equivalence to the legally marketed device.**