MinXray, Inc.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

March 19, 2021

Re: K210479
Trade/Device Name: IMPACT and X-Ranger
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: March 3, 2021
Received: March 9, 2021

Dear Mr. Kamm:

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); labeling (21 CFR Part 801); 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/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 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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K210479

Device Name
IMPACT and X-Ranger

Indications for Use *(Describe)*

This is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities.
The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid.
- Not to be used on bariatric patients, unless imaging body extremities
- Not for mammography use
- This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

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: 510(k) Number K210479

MinXray, Inc.
3611 Commercial Avenue
Northbrook, Illinois 60062, USA
Toll Free 1-800-221-2245 (USA & Canada)
Tel. 1-847-564-0323
Fax 1-847-564-9040

Date Prepared: March 15, 2021

Contact: Keith Kretchmer, President

1. **Identification of the Device:**
   Trade/Device Names: IMPACT and X-Ranger
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile X-Ray System
   Regulatory Class: II
   Product Code: IZL, MQB
   Common/Usual Name: Mobile Diagnostic X-Ray System

2. **Equivalent legally marketed device: K182207**
   Trade/Device Name: TR90BH
   Manufacturer: MinXray, Inc.
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile X-Ray System
   Regulatory Class: II
   Product Code: IZL
   Common/Usual Name: Mobile Diagnostic X-Ray System

3. **Reference device: The IMPACT and X-Ranger use the same digital receptor panel and software, unmodified, as found in:**
   Trade/Device Name: CMDR 2CW
   Submission: K191451
   Manufacturer: MinXray, Inc.
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile x-ray system
   Regulatory Class: II
   Product Codes: IZL, MQB, and LLZ.
   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

4. **Indications for Use (intended use): This is a portable X-ray system with following limitations of use:**
   The device may be used for handheld diagnostic imaging of body extremities.
   The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities.
   The device may be used for stand mounted imaging of the chest when used without a grid.
   - Not to be used on bariatric patients, unless imaging body extremities
   - Not for mammography use
   - This device is not intended to replace a stationary radiographic system, which may be required for

full optimization of image quality and radiation exposure for different exam types.

5. **Description of the Device: This is a complete portable battery operated digital x-ray system with the indications for use stated above. It consists of the battery operated generator described in K182207 paired with the wireless battery operated digital x-ray acquisition components described in K191451. This is therefore a new combination of all previously cleared components. The digital x-ray receptor system uses a wireless panel and a Dell laptop computer fitted with a 300Mbps Mini Wireless N USB Adapter. The generator can be hand held (within the limitations of the indications), tripod mounted, or mobile stand mounted. Two models are proposed: IMPACT and X-RANGER. The two models differ in their targeted markets and in the type of computer supplied. The IMPACT uses a DELL PRECISION 3550 Laptop whereas the X-RANGER uses a DELL LATITUDE 7424 RUGGED LAPTOP. The IMPACT is aimed at the commercial market whereas the X-RANGER is aimed at the military market. The software is unmodified from that employed in our reference device (K191451) and it remains at a moderate level of concern. The image receptor (cleared under K191451) is wireless and measures 14x17 inches.**

6. **Safety and Effectiveness, comparison to predicate device. The results of bench testing indicates that the new device is as safe and effective as the predicate device. Proper system operation is fully verified upon installation.**

7. **Substantial Equivalence Chart: Below.**

	TR90BH K182207	**IMPACT AND X-RANGER**
Intended Use:	The TR90BH is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities. The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. – Not to be used on bariatric patients, unless imaging body extremities – Not for mammography use – The TR90BH is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	The same, only the model number is changed. This is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities. The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. - Not to be used on bariatric patients, unless imaging body extremities - Not for mammography use - This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.
Generator Characteristics		
Weight:	7.5kgs	SAME
Size /	219 x 350 x 190 mm	SAME
Energy Source:	Lithium-ion Rechargeable Battery (57.6DC), 300 exposures per charge.	SAME

	TR90BH K182207	IMPACT AND X-RANGER
Use Interface:	Soft touch push buttons	SAME
Exposure times:	0.01 sec – 1.0 sec : 0.01 sec Step High Power Mode 0.01 sec – 0.3 sec : 0.01 sec Step	SAME
mA:	20 mA @ 40 kVDC – 60 kVDC (2 kVP steps) 15 mA @ 62 kVDC – 80 kVDC (2 kVP steps) 10 mA @ 82 kVDC – 90 kVDC (2 kVP steps) High Power Mode 15 mA @ 82 kVDC – 90 kVDC (2 kVP steps)	SAME
Memory settings (technique)	5 memories via pushbutton	SAME
HF Generator	High Frequency	SAME
kW	1.35 kW	SAME
kVp:	40 – 90kVp	SAME
X-ray Tube	D-0814	SAME
FDA Performance Standard	Complies	SAME
Collimator	Mikasa BLD34L	SAME
Digital Image Capture		
Panel	Not supplied	Same as used in our reference device K191451, 14” x 17” Wireless Pixel Pitch 154 µm 2304 × 2816 pixels
Panel Performance	Not supplied	Panel MTF ~63%.....(@ 1lp/mm) Panel DQE~62%.....(@ 0lp/mm)
Software	Not supplied	Same as used in our reference device K191451

	TR90BH K182207	IMPACT AND X-RANGER
Photo		

8. **Summary of non-clinical testing: The following testing still applies to our predicate generator since it has not been modified: Software validation and risk analysis was performed. Laboratory testing was performed according to the following standards:**

IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-1-2:2007 Medical Electrical Equipment-Part 1-2: General Requirements for Safety – 2. Collateral Standard-Electromagnetic compatibility – Requirements and tests
IEC 60601-1-3:2008 (Second Edition) for use with IEC 60601-1: 2005 (Third Edition) Medical electrical equipment Part 1-3: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment
IEC 60601-1-6:2010 (Third Edition) for use in conjunction with IEC 60601-1: 2005 (Third Edition)Medical electrical equipment Part 1-6: General requirements for safety – Collateral Standard: Usability
IEC 60601-2-28:2010 (Second Edition) for use in conjunction with IEC 60601-1: 2005 (Third edition) Medical electrical equipment Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-54 (First Edition): 2009 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC 62304:2006 (First Edition) Medical device software: Software life-cycle processes
IEC 62366: 2007 (First Edition) + A1: 2014 Medical devices – Application of usability engineering to medical devices.

The test results showed compliance with the above standards. We also confirmed overall operation by taking and reviewing test images using the imaging system and software from our reference device.

Previously performed: Battery performance testing: A 3rd Party Testing Lab was engaged to do safety performance testing on the rechargeable lithium-ion battery pack, done according to the United Nations "Recommendations on the Transport of Dangerous Goods Manual of Tests and Criteria." The following testing was successfully performed: Altitude simulation, Thermal test, Vibration, Shock, External short circuit, Impact, Overcharge, and Forced discharge. In addition, battery life testing was performed to establish how many x-ray exposures can be made on one battery charge. The AC/DC adapter used with the battery charger is medical grade UL Listed (E356265).

During the original design process, we took the following FDA guidance into account: *Guidance for Industry and FDA Staff Radiation Safety Considerations for X-Ray Equipment Designed for Hand-Held Use; Document issued on December 24, 2008*. This involved employing extra shielding and precautionary information in the labeling**.**

For the modified system representing the combination of our predicate generator and our reference imaging system, we performed integration and usability testing to confirm the ability of the user to assemble, operate, and get diagnostic images using our reference digital imaging components. Assembly and system test procedures have been written and approved.

9. **Summary of clinical testing: Not applicable. Clinical testing was not deemed to be required to show substantial equivalence. We relied on non-clinical testing and compliance with standards.**

10. **Conclusion: After analyzing bench tests, it is the conclusion of MinXray Inc. that the IMPACT AND X-RANGER Portable X-Ray Equipment is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**