December 14, 2018

MinXray, Inc
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES, FLORIDA 34114

Re: K182207
Trade/Device Name: TR90BH
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: October 9, 2018
Received: October 22, 2018

Dear Daniel 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/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,

for
Robert A. 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)*
K182207

Device Name
TR90BH (Portable Diagnostic X-Ray System)

Indications for Use *(Describe)*

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.

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 K182207

MinXray, Inc.
3611 Commercial Avenue
Northbrook, Illinois 60062, USA
Toll Free 1-800-221-2245 (USA & Canada)

Date Prepared: December 11, 2018

Contact: Keith Kretchmer, President

1. **Identification of the Device:**
   Trade/Device Names: TR90BH
   Regulation Number: 21CFR892.1720
   Regulation Name: Mobile X-Ray System
   Regulatory Class: II
   Product Code: IZL
   Common/Usual Name: Mobile Diagnostic X-Ray System

2. **Equivalent legally marketed device: K153059**
   Trade/Device Name: HF1202H PowerPlus™ Portable X-Ray Equipment
   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. **Indications for Use (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.

4. **Reference Device:** MinXray Model HF80H cleared for general purpose radiography in K945707. This device provides a range of technique factors closely comparable to the new TR90BH but using older technology. The HF80H was a 10 mA model. It was soon followed by a 15 mA model known as the HF80H+. FDA advised us that it was not necessary to submit a new 510(k) when we released HF80H+ with 15 mA and the same kV range. The concern is that higher mAs factors needed for properly imaging thicker body parts (e.g. chest, abdomen) would need to be achieved via longer exposure times leading to patient motion artifact, but this reference device has a fixed ma capability of 15 ma and a maximum kVp of 80, whereas the new TR90BH has the same ma capability of 15 mA at a maximum kVp of 90. Therefore longer exposure times would not be needed with the new device as compared to this reference device. The same Technique Chart we provided for the HF80H+ could be used for the TR90BH. The new device does have higher mA capability, 20 mA at up to 60 kVp. A comparison chart follows.

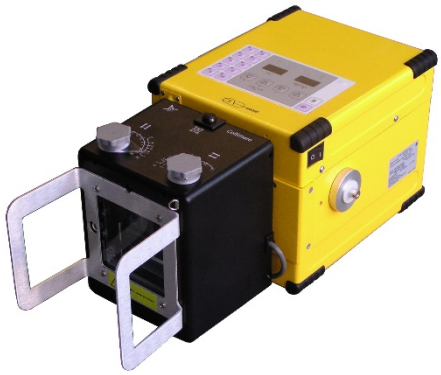
	HF80H+ K945707	TR90BH K182207
mA & kVp	15 mA, fixed 50-80 kVp	20 mA @ 40 kVDC – 60 kVDC (2 kVP steps) 15 mA @ 62 kVDC – 80 kVDC (2 kVP steps) 10 mA @ 82 kVDC – 90 kVDC (2 kVP steps) High Power Mode 15 mA @ 82 kVDC – 90 kVDC (2 kVP steps)
Exposure times	0.08-3.98 sec, 0.02 steps.	0.01-1.0 sec in 0.01 sec steps. High Power Mode 82-90 kV @ 15 mA the maximum exposure time is 0.30 sec.

5. **Description of the Device:** We have developed compact, lightweight, battery powered easy-carry TR90BH based on the technology of HF1202H. This device can be used with a stand or hand-held. A detailed comparison table with an equivalent device is provided below. The MinXray TR90BH consists of a battery powered X-ray generator (tubehead/control), continuously adjustable light beam collimator, mounting trunnion, exposure cord with 2-stage exposure switch, battery, battery charger, AC adaptor and AC power cord, and those are provided in a portable carry case with wheels. If a stand is purchased with the TR90BH, such as the MinXray XGS series of gas spring portable mobile stands, instructions for assembly of the stand and the attachment of the TR90BH are included with the stand. The device works with a dedicated secondary Lithium-ion battery, therefore it can be operated at no power supply places such as disaster sites. A few number of shots can be taken in short charge time thanks to the newly designed and superior patent licensed battery. The x-ray tube is Toshiba Electron Tubes & Devices D-0814 0.8mm, 9.86kHU which is designed for diagnostic x-ray applications. 2-stage exposure switch: The exposure switch has 2-stage button. The first stage preheats the filament of the x-ray tube and lights collimator enabling operator to confirm exposure area. After keeping the button position at the first stage end for approximately 1 second, exposure preparation will be done and the STAND BY indicator will light. The second stage initiates the x-ray exposure for the time set in the sec display in advance. When the second stage is fully pressed, x-ray will be emitted, the X-RAY indicator will light, and an audible signal will be heard. One must PRESS AND HOLD THE SECOND STAGE END POSITION UNTIL THE EXPOSURE HAS TERMINATED. The switch operates in a "dead man" mode in that x-ray exposure will terminate immediately as a safety feature when the button is released.
   Technology: The basic technology has not changed, however the TR90BH uses a new designed secondary battery unit. Our labeling shows that it is possible to operate the unit in a "hand held" mode. 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. The software and microprocessors are the same as those used in our predicate design, with a moderate level of concern applicable to this kind of software. A power-on password routine has been added to address cybersecurity concerns. This would prevent unauthorized use of the device.

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.

	HF1202H PowerPlus™ K153059	TR90BH
Intended Use:	This radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammographic 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.
Comment on Indications	Original Indications	Certain limitations apply because of the lower maximum kVp output as compared to the predicate and because of the possibility of handheld use on extremities. See indications above.
Weight:	19.5kgs	7.5kgs
Size /	305 x 460 x 225 mm	219 x 442 x 190 mm
Energy Source:	120/240 V 50 – 60AC	Lithium-ion Rechargeable Battery (57.6DC), 300 exposures per charge.
Use Interface:	Soft touch push buttons	SAME
Exposure times:	(0.02– 0.2sec) in 0.01sec. Step (0.2-0.4sec) in 0.02sec. Step (0.4-1.0sec) in 0.05sec Step (1.0-5.0sec) in 0.1sec Step	0.01 sec – 1.0 sec : 0.01 sec Step High Power Mode 0.01 sec – 0.3 sec : 0.01 sec Step
mA:	60 mA(0.02-0.05sec), 45mA (0.06 –0.2sec), 33 mA(0.22-5.0sec), @ 40 – 60 kVDC 55 mA(0.02-0.05sec), 41.3mA (0.06 –0.2sec), 30.3 mA(0.22-5.0sec), @ 62 – 70 kVDC 50 mA(0.02-0.05sec), 37.5mA (0.06 –0.2sec), 27.5 mA(0.22-5.0sec), @ 72 – 80 kVDC 45 mA(0.02-0.05sec), 33.8mA (0.06 – 0.2sec), 24.8 mA(0.22-5.0sec), @ 82 – 90 kVDC 40 mA(0.02-0.05sec), 30.0mA (0.06 – 0.2sec), 22.0 mA(0.22-5.0sec), @ 92 – 100 kVDC 30 mA(0.02-0.05sec), 22.5mA (0.06 – 0.2sec), 16.5 mA(0.22-5.0sec), @ 102 – 110 kVDC 25 mA(0.02-0.05sec), 18.8mA (0.06 –0.2sec), 13.8 mA(0.22-5.0sec), @ 112 – 120 kVDC	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) Comment: 90 kVP maximum instead of 120 kVP maximum.

	HF1202H PowerPlus™ K153059	TR90BH
Memory settings (technique)	10 memories via pushbutton	5 memories via pushbutton
HF Generator	High Frequency	SAME
kW	1.5 kW	1.35 kW
kVp:	40 – 120kVp	40 – 90kVp
X-ray Tube	SXR 130-15-1.2	D-0814
FDA Performance Standard	Complies	Complies
Collimator	Collimare®	Mikasa BLD34L
Photo		

8. **Summary of non-clinical testing: The software is unchanged with a moderate level of concern. 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.

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 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. Meets the US Performance standard on leakage.

9. **Summary of clinical testing:** A limited clinical test was performed to demonstrate that the device could image anatomy other than extremities. A Board Certified Radiologist performed a successful review.

10. **Conclusion: After analyzing bench and clinical testing, it is the conclusion of MinXray Inc. that the TR90BH Portable X-Ray Equipment is as safe and effective as the predicate device, has few technological differences, and has similar indications for use, thus rendering it substantially equivalent to the predicate device.**