



Food and Drug Administration
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Silver Spring, MD 20993-0002

February 2, 2016

MinXray, Inc.
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K153059

Trade/Device Name: HF1202H PowerPlus™ Portable X-ray Equipment
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: October 19, 2015
Received: October 21, 2015

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. 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,



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)

K153059

Device Name

HF1202H PowerPlus(tm) Portable X-ray Equipment

Indications for Use (Describe)

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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: 510(k) Number K153059

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Date Prepared: January 25, 2016

Contact: Keith Kretchmer, President

1. Identification of the Device:

Proprietary-Trade Name: HF1202H PowerPlus™ Portable X-Ray Equipment

2. Classification Name: Mobile x-ray system, Product Code IZL Regulation Number 892.1720

Common/Usual Name: Mobile Diagnostic X-Ray System

3. Equivalent legally marketed device: K040046, MinXray HF120/60 PowerPlus,™ made by Mikasa X-Ray Co. Ltd. (for MinXray). Mobile x-ray system, Product Code IZL Regulation Number 892.1720

4. Indications for Use (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.

5. Description of the Device: The MinXray HF1202 consists of an X-ray generator (tubehead/control), continuously adjustable light beam collimator, mounting trunnion, exposure cord with 2-stage exposure switch, and AC power cord. If a stand is purchased with the HF1202, such as the MinXray XGS series of gas spring portable mobile stands, instructions for assembly of the stand and the attachment of the HF1202 are included with the stand. This is a high-frequency generator of updated design. The unit has a serial port and a Bluetooth port for communication of technique factors to a PC. The PC cannot initiate an exposure. When used, the PC must employ FDA cleared software and digital receptor panels. Known compatible with Toshiba FDX4343RP and FDX4343RPW digital x-ray panels. The FDX4343RP was cleared in K130883 (and K131211) and the FDX4343RPW was cleared in K143257.

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

	K040046, MinXray HF120/60 PowerPlus,™ made by Mikasa X-Ray Co. Ltd. (made for MinXray)	HF1202H PowerPlus™ Portable X-Ray Equipment
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. Language later required by FDA)	(SAME) 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.
Size / weight:	453 x 292 x 224 mm 17.94kgs	460 x 305 x 225 mm 19.5kgs
Energy Source:	120V 50 – 60AC	SAME

	K040046, MinXray HF120/60 PowerPlus,™ made by Mikasa X-Ray Co. Ltd. (made for MinXray)	HF1202H PowerPlus™ Portable X-Ray Equipment
Use Interface:	Up-Down pushbuttons for kVp selections and exposure time selections and exposure time selections with LED indicators mAs indicator.	SAME
Exposure times:	(0.01– 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	(0.02– 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
mA:	60 mA(0.01-0.1sec), 42 mA (0.11 – 5.0sec) @ 40 - 50 kVDC 50 mA(0.01-0.1sec), 35 mA (0.11 –5.0sec) @ 52 - 60 kVDC 45 mA(0.01-0.1sec), 31.5 mA (0.11– 5.0sec) @ 62 - 70 kVDC 38 mA(0.01-0.1sec), 26.6 mA (0.11– 5.0sec) @ 72 - 80 kVDC 33 mA(0.01-0.1sec), 23.1 mA (0.11–5.0sec) @ 82 - 90 kVDC 30 mA(0.01-0.1sec), 21 mA (0.11 –5.0sec) @ 92 - 100 kVDC 20 mA(0.01-0.1sec), 14 mA (0.11–5.0sec) @ 102 - 120 kVDC	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
Memory settings (technique)	5 memories via pushbutton	10 memories via pushbutton
HF Generator	85 kHz	SAME
kW	2.4 kW peak	3.0 kW peak
kVp:	40 – 120kVp	SAME
X-ray Tube	Superior X-ray Tube Company SXR-130 1.2 mm, 65 kHU	SAME
Collimator	Advantech	Collimare®
Serial Communication	Not available	RS-232 or Bluetooth for communication of technique factors to a PC.

	K040046, MinXray HF120/60 PowerPlus,™ made by Mikasa X-Ray Co. Ltd. (made for MinXray)	HF1202H PowerPlus™ Portable X-Ray Equipment
Photo		

8. Summary of non-clinical testing: 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 including IEC 62366: Application of usability engineering to medical devices
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 these standards. We also confirmed overall operation by taking and reviewing test images; however, sample clinical images were not required to determine substantial equivalence. The Bluetooth® module is FCC approved and was validated for use with the HF1202H.
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 HF1202H PowerPlus™ Portable X-Ray Equipment is as safe and effective as the predicate device, has the same indications for use, has few technological differences, which are addressed through performance testing and compliance with the standards listed above, thus rendering it substantially equivalent to the predicate device.