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EXHIBIT 2 K040046

Mikasa X-Ray Co., LTD. **(Manufacturer)** **13-2, Hongo 3-chome** **Bunkyo-Ku, Tokyo 113-0033 Japan** **Tel 81-3-3813-3911** **Fax 81-3-3813-4420**	**MinXray, Inc** **(Initial Distributor)** **3611 Commercial Ave.** **Northbrook, IL 60062** **Tel 847-564-0323** **Fax 847-564-9040** **Contact: Keith Kretchmer**

January 6, 2004

510(k) Summary

1. **Identification of the Device:**
   Proprietary-Trade Name: *MinXray HF120/60H PowerPlus*™ High Frequency Diagnostic X-Ray Unit"
   Classification Name: Mobile X-ray system, Product Code 90 IZL
   Common/Usual Name: Portable general purpose diagnostic X-ray Unit.

2. **Equivalent legally marketed devices** This product is similar in function to the MinXray HF100H (a pre-amendments device)

3. **Indications for Use (intended use)** The *MinXray HF120/60H PowerPlus*™ is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

4. **Description of the Device:** *MinXray HF120/60H PowerPlus*™ is a portable unit which operates from 120 V 50-60~ AC. The unit utilizes a newly designed high frequency inverter and can be mounted to a tripod or support arm. The usual safety precautions regarding the use of x-rays must be observed by the operator.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate device.

6. Substantial Equivalence Chart, *MinXray HF120/60H PowerPlus™*

Characteristic	MinXray HF100H (Pre-amendments device)	*MinXray HF120/60H PowerPlus™*
Intended Use:	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	SAME
Physical characteristics:		
Size/weight	406 x 222 x 241 mm 18.6 kg	406 x 221 x 240 mm, 20 kg.
Energy Source:	120 v 50-60~ AC	SAME
User Interface	Up-Down pushbuttons for three kVp selections and exposure time selections with LED indicators	Up-Down pushbuttons for kVp selections and exposure time selections with LED indicators mAs indicator
Exposure times	199 (in 0.01 sec. Steps) 0.08 - 4.00 sec.	(0.01 - 0.2 sec) (in 0.01 sec. Step) , (0.2 - 0.4 sec) (in 0.02 sec. Step) (0.4 - 1.0 sec) (in 0.05 sec. Step), (1.0 - 5.0 sec) (in 0.1 sec. Step)
Ma.	20 mA constant	30 mA(40-60kV) 25mA(62-80kV) 20mA(82-100kV)
KvP	40-100 KvP	Max. 120 KvP
Standards and Safety characteristics:		
Performance Standard	21 CFR 1020.30	SAME
Electrical safety:	UL 2601, IEC 60601-1	SAME, plus UL listed

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of MinXray that the *MinXray HF120/60H PowerPlus™* is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device. Safety is further assured by Underwriters Laboratories testing and listing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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MinXray, Inc.
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K040046
Trade/Device Name: MinXray HF120/60H PowerPlus™
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: January 6, 2004
Received: January 13, 2004

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

j) Indications for Use

510(k) Number K040046

Device Name: *MinXray HF120/60H PowerPlus™*

Indications for Use: The *MinXray HF120/60H PowerPlus™* is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040046