K060566

APR 5 2006

EXHIBIT 2

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

February 25, 2006

510(k) Summary

1. **Identification of the Device:**
   Proprietary-Trade Name: *MinXray HFP24 and HFP40* High Frequency Diagnostic X-Ray Units
   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 P200 R24/40 (pre-amendments devices) and MinXray HF100H+ (K052721)

3. **Indications for Use (intended use)** The MinXray HFP24 and HFP40 is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. These units are specifically designed for podiatric and extremity applications.

4. **Description of the Device:** MinXray HFP24 and HFP40 are x-ray units which operate from 120 V 50-60~ AC. They utilize a newly designed high frequency inverter designed to be mounted on a stand. 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 HFP24 and HFP40**

Characteristic	MinXray P200 R24/40 (pre amendments)	MinXray HF100H+ (K052721)	Minxray HFP24/40 (Modified Device)
Intended Use :	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	SAME	SAME
Physical characteristics			
Size/weight	171 x 330.2 x 175.5 mm (P200R24)13kgs 216 x 330.2 x 190.5 mm (P200R40)15kgs	406 x 222 x 241 mm 18.6kgs	230 x 195 x 380 mm (HFP24)9.3kgs 230 x 195 x 390 mm (HFP40)12.5kgs
Energy Source	110-130V 60Hz AC1.0kVA	100-140V 50-60 Hz 3.0kVA	100-140V 50-60Hz 1.5kVA
Mounting Method	P200R24 Stationary system P200R40 Mobile system	Unit is usually mounted to a MinXray XGS MKIII Portable Stand	SAME as P200R24/40

Characteristic	MinXray P200 R24/40 (pre amendments)	MinXray HF100H+ (K052721)	Minxray HFP24/40 (Modified Device)
Technical characteristics			
User Interface	Knob for kVp selections and exposure time selections	Up-Down pushbuttons for kVp selections and exposure time selections with LED indictors and mAs indicators	SAME as HF100H+
Exposure switch	Single-stage deadman type	Dual-stage, deadman type	SAME as HF100H+
Controls	Analog	Software based, 2 CPUs.	SAME as HF100H+
Construction	Monobloc generator, Medical high tension transformer system	Monobloc HF generator, Medical full bridge inverter system	SAME as HF100H+
High Voltage Energy Source	conventional transformer	High frequency (60kHz) inverter	SAME as HF100H+
Line Voltage adjustment	manual	Automatic, dynamic	SAME as HF100H+
Exposure times	0.08-2.0 sec(16 Steps)	0.03-0.2 sec(in 0.01 sec. Steps) 0.2-0.4 sec(in 0.02 sec. Steps) 0.4-1.0 sec(in 0.05 sec. Steps) 1.0-4.0 sec(in 0.1 sec. Steps)	0.03-0.2 sec(in 0.01 sec. Steps) 0.2-0.4 sec(in 0.02 sec. Steps) 0.4-1.0 sec(in 0.05 sec. Steps) 1.0-2.0 sec(in 0.1 sec. Steps)
Tube potential (kV)	63kV constant	40 - 100kV 2kVstep	50 - 70kV 2kVstep
kV steps	constant	31(2kV-step)	11(2kV-step)
Tube current (mA)	12mA	30mA(40-60kV) 25mA(62-80kV) 20mA(82-100kV)	10 mA
X-ray tube	Toshiba D-102	Toshiba D-124S	SNMIF XDT-S70
Anode heat Storage	20,000 HU	20,000 HU	20,000 HU
Focal Spot Size	1.0 mm	1.2 mm	0.8 mm
mAs	0.96-24mAs	0.6-120mAs	0.3-20mAs
Total filtration	P200R24 2.7 mm AL equivalent P200R40 3.2 mm AL equivalent	3.2mm AL equivalent	SAME as P200
Collimator	P200R24 Advantech R72 P200R40 MIKASA R-200H	Advantech R72 Continuously adjustable light beam type with central x-ray indicator	SAME as P200
Source to Skin Distance (SSD)	P200R24: 24 inches P200R40: 40 inches	300 mm	SAME as P200

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of MinXray that the *MinXray HFP24 and HFP40 High Frequency Diagnostic X-Ray Units* are as safe and effective as the predicate devices, have few technological differences, and has no new indications for use, thus rendering them substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 5 2006

MinXray, Inc.
% Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K060566
Trade/Device Name: MinXray HFP24 and HFP40
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: February 25, 2006
Received: March 7, 2006

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 (Premarket Approval), 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K060566

Device Name: MinXray HFP24 and HFP40

Indications For Use:

The MinXray HFP24 and HFP40 is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. These units are specifically designed for podiatric and extremity applications.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060566