

K 973712



EXHIBIT A

DEC 12 1997

510(k) Summary of Safety and Effectiveness

1. Identification of the Device

Classification Name: 90 IZL per 21 CFR 892.1720

Common/Usual Name: Portable general purpose diagnostic X-ray unit.

Proprietary Trade Name: MinXray HF100H High Frequency Diagnostic X-ray Unit

2. Equivalent legally marketed device

This product is similar in design and function to the MinXray HF80H High Frequency Diagnostic X-ray Unit (K945707).

3. Indications for Use (intended use)

The MinXray HF100H will be initially marketed for portable and mobile general purpose diagnostic medical radiography. Because of its compact size and high output to weight ratio, we anticipate that the initial uses will be in field, home care, and nursing home diagnostic radiographic applications. These uses are typical of the predicate device, the MinXray HF80H. We believe that the safety and effectiveness of the two models are substantially equivalent.

Experience in the market with the HF100H may make us aware of other possible applications. This unit may be eventually married with stands for permanent or semi-permanent installation for intra-operative use, hand and/or foot radiography, or other medical diagnostic applications. MinXray will make some stands available as accessory items for use with the HF100H. Other manufacturers may make stands compatible with various portable X-ray units, and we anticipate that some end users will purchase a MinXray HF100H to be used with some other stand of their choice.

4. Description of the device

The MinXray HF100H is a compact, self-contained high frequency X-ray unit consisting of the control, X-ray generator, and beam limiting device. Tube voltage (kV) and exposure time are variable and selected by the operator. Tube current is fixed at 20 mA.

5. Safety and Effectiveness, comparison to predicate device

The MinXray HF100H is substantially equivalent to the MinXray HF80H in safety and effectiveness. Preproduction testing showed that radiographs of the same patient produced on either device were essentially identical. The following chart compares the new and predicate devices.

6. Substantial Equivalence Chart

<u>Feature</u>	<u>MinXray HF100H (new device)</u>	<u>MinXray HF80H (predicate)</u>
X-ray output	20 mA @ 40-100 kV in 2 kV steps	10 mA @ 50-80 kV in 5 kV steps
Timer	0.08-2.00 sec. 192 steps	0.08-3.98 sec. 195 steps
X-ray generator	Constant potential, 60 kHz Full-wave rectified	Constant potential, 45 kHz Full-wave rectified
Line voltage adjustment	Automatic, dynamic	Automatic, dynamic
X-ray tube	Toshiba D-124K or equiv.	Toshiba D-102 or equiv.
Focal spot size	1.2 mm	1.0 mm
Total filtration	3.2 mm Al equivalent	3.2 mm Al equivalent
Collimator	Advantech R-70ET or equiv.	Advantech R-70ET or equiv.
Exposure cord	8 feet (2.44 meters)	8 feet (2.44 meters)
Exposure switch	Two-stage, deadman type	Two-stage, deadman type
Power cord	10 feet (3.05 meters)	10 feet (3.05 meters)
Overload protection	Thermal, built-in	Thermal, built-in
Size (tubehead/control)	9.5" (24.1 cm) W, 8.75" (22.2 cm) H, 15.35" (39 cm) L + skin guards	6.5" (16.5 cm) W, 7.5" (19 cm) H, 14.5" (27.94 cm) L + skin guards
Weight	40.9 lbs (18.6 kgs)	27.5 lbs (12.5 kgs)
Control display	Digital	Digital

7. Conclusion

Since there are no new indications for use, nor are there any new potential hazards, and preproduction testing showed that radiographs of the same patient produced on either device were essentially identical, MinXray is of the opinion that the devices are substantially equivalent.



8. Manufacturer's Statement of Substantial Equivalence

STATEMENT OF INDICATIONS FOR USE:

The MinXray HF100H will be initially marketed for portable and mobile general purpose diagnostic medical radiography. These uses are typical of the predicate device, the MinXray HF80H.

CLAIMS REGARDING DEVICE FEATURES, PERFORMANCE, OR SAFETY:

This product is similar in design and function to the MinXray HF80H high frequency diagnostic X-ray unit (K945707).

This notification contains all of the information required by 21 CFR 807.87. A completed copy of the "DRAERD Premarket Notification 510(k) Screening Checklist" is attached.

The subject device conforms to the following mandatory standards:

Performance Standard: 21 CFR 1020.30 Diagnostic X-ray Systems

The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of action are equivalent. If the subject device is a kit, all of the contents of the kit are either pre-Amendment devices or have been cleared for marketing through previous 510(k)s. The kit contains no drug or biologic product.

The subject device is not software controlled.

TRUTHFUL AND ACCURATE STATEMENT (as required by 21 CFR 807.87(j)):

I certify that, in my capacity as President of MinXray, Inc., I believe, to the best of my knowledge, that the above statements and all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Keith R. Kretchmer
President

9/26/97
Date

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

Keith R. Kretchmer
President
MinXRay, Inc.
3611 Commercial Avenue
Northbrook, IL 60062-1822

Re: K973712
MinXray HF100H High Frequency
Diagnostic X-Ray Unit
Dated: December 5, 1997
Received: December 8, 1997
Regulatory Class: II
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Kretchmer:

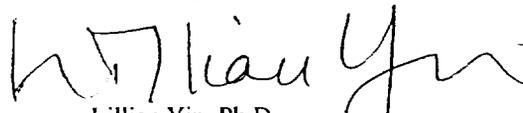
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

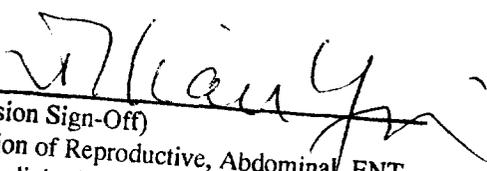
Enclosure

EXHIBIT B

Indications for Use (intended use)

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(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973712

Prescription Use
(Per 21 CFR 801.109)