

K 981466

JUL 14 1998

510 (k) Summary

Submitters Information

Name: Imaging Sciences International Inc.

Address: 941 Hamilton Ave.
Roebing NJ, 08554

Phone Number: 609-499-3700

Fax Number: 609-499-8833

Person To Contact: Robert E. Hay
Radiation Safety Officer

Date Of Summary: April 17, 1998

Trade Name Of The Device: XR-910

Common Or Usual Name: Mobile X-Ray Unit

Classification Name: X-Ray, Mobile

Substantial Equivalence Claim: The Imaging Sciences International Inc. XR-910 Mobile X-Ray unit is substantially equivalent to the DynaRad Corporation Phantom Portable X-Ray system.

Description Of The Device: The XR-910 Mobile X-Ray unit is a light weight (78 pounds), compact (20" W 54.5" L 21" H), X-Ray System. The system can be easily loaded into a van or similar vehicle for transporting to the site where the unit will be used.

Intended Use Of The Device: The XR-910 is easily transported by a van or similar vehicle, to a private residence, nursing home, medical clinic, and other such facilities. With the large 15" pneumatic wheels, and 20" wheel-base and a weight of only 78 lbs., the XR-910 can be easily maneuvered through doorways, hallways, and up and down flights of stairs. This can be accomplished by an average person. Due to the large vertical movement of the tubehead and boom arm, and rotational positions of the tubehead, radiographs may be taken with the patient standing, sitting or supine. Radiographs may be taken of the chest and extremities. The XR-910 is a 50 to 90 kVp, 10 mA unit. Using 800 speed film and screens, exposure times for most radiographs are less than 100 milliseconds.

Technological Characteristics Of The Device: The XR-910 technology is based on the Keystone X-Ray *Intrex VSK*, 510 (k) Number K931486.

The basic power supply consists of a full wave bridge rectifier, so connected that it may be operated on either 120 VAC or 220 VAC, 50 - 60 Hz power lines. This accomplished by changing jumpers in the power supply.

At the output of the bridge rectifier, two very high capacity 250V filter capacitors smooth the rectified power, which is then presented to a voltage regulator, consisting of five transistors, amplifiers and a reference diode. This regulator regulates the voltage applied to a four diode transistor inverter chopper.

Another low voltage power supply, with its step down transformer, bridge rectifier, and associated filters, supply power to another regulator and a logic board, so connected as to control the technique factors and the "on - off" exposure of the X-Ray System.

The inverter is supplied by a 20 KHz signal that is developed on the logic board. This 20KHz alternately turns on and off the inverter to chop the DC power that has been generated in the power supply.

The 20KHz square wave is now transformed into 200 volt positive and negative pulses, this signal is then sent to the tubehead. In the tubehead the signal is supplied to a power output transformer, which raises the 200 volts to 6,000 volts. This 6,000 volts is now applied to a plus and minus multiplier PC boards. With its associated diodes and capacitors, the multiplier boards raise the 6,000 volt square wave to plus 35,000 and minus 35,000 volts. An X-Ray tube is placed between the two multiplier board outputs creating a potential across the X-Ray of 70,000 volts. The 20 KHz, 200 volt square wave may be adjusted upward and downward to create a kVp range from 50 kVp to 90 kVp in 1 kVp increments.

The filament of the X-Ray tube is also heated by the 20 KHz signal taken directly from the oscillator on the logic board. A rheostat is placed in series with the filament transformer, so it may be shunted out for fast heating of the filament, and switched back in during the exposure.

A voltage divider in the multiplier circuit of the tubehead allows the monitoring of the kVp. A current sample obtained from the primary of the power transformer allows the mA to be proportionately monitored within a 10% accuracy.

Two timers are included on the Timer PC board. One of the timers delays the exposure turn on until the filament has reached sufficient operating temperature. The second timer times the length of the desired exposure. The exposure time is can be programmed from 0.01 to 4.0 seconds in increments of 0.01 seconds. The clock for these timers operates at 1,000 KHz, and is divided down on the logic PC board:

In operation when, the exposure switch push button is depressed, the delay timer starts counting down a preprogrammed time that allows the filament to heat up to its proper temperature. When the delay timer has timed out the countdown of the exposure timer starts. At the end of the exposure, the exposure timer signals the inverter logic to cease operation, thereby shutting down both the high voltage anode and filament supplies, terminating the exposure.

Assessment of Non-Clinical Performance: During the evaluation process, the XR-910 Mobile X-Ray System was transported throughout various parts of our building. With the large 15" pneumatic wheels, a narrow 20" wheelbase and a weight of only 78 lbs., the unit was maneuvered through doorways, across concrete floors, carpeted floors and up and down stairways with relative ease.

During the evaluation, the 90 kVp Constant Potential and 10 mA of the XR-910 produced radiographs of a step wedge and a phantom that were comparable with the DynaRad unit, and adequate for their intended use.

Conclusions of Non-Clinical Performance: The performance of the XR-910 during the non-clinical evaluation would indicate that the system is substantially equivalent mechanically, electrically and radiographically to the DynaRad Phantom Portable X-Ray system.



JUL 14 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Robert E. Hay
Radiation Safety Officer
Imaging Sciences International Inc.
941 Hamilton Avenue
Roebling, NJ 08554-0117Re: K981466
XR-910 (Mobile X-Ray Unit)
Dated: April 17, 1998
Received: April 23, 1998
Regulatory class: II
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Hay:

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 requirements, 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/dsma/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

510(k) Number (if known): _____

Device Name: _____ **XR-910 Mobile X-Ray Unit**

Indications For Use: **Indications for Use**

The XR-910 folds into a compact unit (20" W 54.5" L 21" H). The XR-910 is then easily transported by a van or similar vehicle, to a private residence, nursing home, medical clinic, and other such facilities. With the large 15" pneumatic wheels, and 20" wheelbase and a weight of only 78 lbs., the XR-910 can be easily maneuvered through doorways, hallways, and up and down flights of stairs. This can be accomplished by an average person. Due to the large vertical movement of the tubehead and boom arm, and rotational positions of the tubehead, radiographs may be taken with the patient standing, sitting or supine. Radiographs may be taken of the chest and extremities. The XR-910 is a 60 to 90 kVp, 10 mA unit. Using 800 speed film and screens, exposure times for most radiographs are less than 100 milliseconds.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K981466

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____