



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB - 2 2004

Mr. John Lee  
President  
United Radiology Systems, Inc.  
151 South Pfingsten Road, Unit T  
DEERFIELD IL 60015

Re: K032628  
Trade/Device Name: PXP-HF 15/20/40 Portable X-Ray  
Regulation Number: 21 CFR 892.1720  
Regulation Name: Mobil x-ray system  
Regulatory Class: II  
Product Code: 90 IZL  
Dated: December 15, 2003  
Received: December 16, 2003

Dear Mr. Lee:

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.

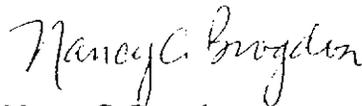
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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  
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): K032628

Device Name: PXP-HF 15/20/40 PORTABLE X-RAY SYSTEMS

### Indications For Use:

PXP-HF family of portable X-Ray systems are designed for a general radiographic application in a field or medical clinics use. There are only difference in radiation output and x-ray tube between the portable X-Ray systems.

PXP-20HF and PXP-40HF portables are used with mobile stand systems for Nursing home-care or Private home-care application. When the patients are sick at home, it is very expensive to bring the patients to a hospital by ambulance transportation service for X-ray examination. Therefore hospital sends this portable equipment to the patient's houses and take a X-ray picture on sito. This portable and mobile systems has been used on a battie field because of easy mobility.

PXP-15HF portable X-ray systems has been used for Foot & Hand- care clinics or sport medicine group in sport complex or sport stadium for X-ray examination of athletics who are injured during a game.

Prescription Use   
(Part 21 CFR 801 Subpart D)

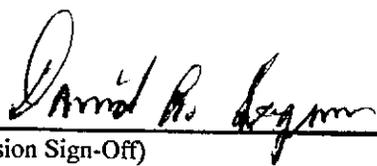
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K032628

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