OCT 7 - 2005

K 052341

EXHIBIT 4 (Page 1 of 2)
510 (k) Summary

August 23, 2005

1. Submitter:

Company:	JPI America, Inc
	141-A Central Avenue
	Farmingdale, NY 11735
Telephone:	631-454-0090
Contact:	Abe Elgohary

2. Identification of Device:

Proprietary-Trade Name:	AJEX 9015H and AJEX 135H Portable X-ray Units
Classification Name:	Mobile X-ray System
Product Code:	90 IZL
Common/Usual Name:	Portable general Purpose X-ray Unit.

3. Equivalent Marketed Devise:

This product is substantially equivalent to the PXP 15/20/40 Portable X-ray units (Predicate Device), which have been found to be substantially equivalent through the 510 (k) premarket notification process.

4. Description of Device:

The AJEX 9015H and AJEX 135H are portable x-ray units which operate at 110V 50/60 HZ. The units have an LED display with up and down soft keys to control KvP. In addition the unit has preset memory keys to store and select KvP. The units can be installed on a mobile stand, a support arm or can be hand held. The unit should be used only by qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of body parts. The usual safety precautions regarding the use of x-ray units must be observed by the operator.

5. Intended Use of AJEX 9015H AND AJEX 135H:

The AJEX 9015/135H Portable X-rays are intended for use in mobile/portable applications, by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of body parts.
-The AJEX 9015H is intended for use by foot and hand care clinics and portable orthopedic needs by sports medicine groups at sports arenas.
-The AJEX 135H is intended for use in mobile applications for off-site patients that are not mobile.

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6. Substantial Equivalence Chart

Model AJEX-9015H AND AJEX-135H

Characteristics	PXP-HF15	PXP-HF20	PXP-HF40	AJEX-9015H	AJEX-135H
Intended use.	Portable general radiographic applications	SAME	SAME	**SAME**	**SAME**
MA	15	20	35	**15**	**35**
kVp	80	90	100	**90**	**100**
Max. output	1.2kW	1.35kW	2.4kW	**1.35kW**	**2.25kW**
Focal Spot	1.2 mm	1.2 mm	1.2 mm	**1.2 mm**	**1.2 mm**
Power requirement	120/220 Vol., 50/60 Hz	120/220 Vol., 50/60 Hz	120/220 Vol., 50/60 Hz	**110 Vol., 50/60 Hz**	**110 Vol., 50/60 Hz**
User Interface	LED display. Up-Down push buttons for kVp selection. With memory key storage.	LED display. Up-Down push buttons for kVp selection. With memory key storage.	LED display. Up-Down push buttons for kVp selection. With memory key storage.	**LED display. Up-Down push buttons for kVp selection. With memory key storage.**	**LED display. Up-Down push buttons for kVp selection. With memory key storage.**
Collimator	Manual 50W Halogen 4 Blade	Manual 50W Halogen 4 Blade	Manual 150W Halogen 4 Blade	Manual 50W Halogen 4 Blade	Manual 100W Halogen 4 Blade
Size	20.32 x22.86x17.78 m	20x32x30 cm	25x20x35cm	**23.8x34x19.4 cm**	**16.5x29x21.5 cm**
Weight	22 Lb.	21 Lb.	28 Lb.	**17 Lb.**	**32 Lb.**

7. Conclusion:

After analyzing all the data it is the conclusion of JPI that the AJEX-9015H and 135H are as safe and effective as the predicate devise. The systems have few technological differences, and have no new indication for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2005

Mr. Abe Elgohary
Vice President
JPI America, Inc.
141-A Central Avenue
FARMINGDALE NY 11735

Re: K052341
Trade/Device Name: AJEX 9015.135H
Portable X-Ray
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: August 23, 2005
Received: August 26, 2005

Dear Mr. Elgohary:

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): K052341

Device Name: AJEX 9015/135H PORTABLE X-RAY

Indications for Use:

The AJEX 9015/135H Portable X-rays are intended for use in general radiographic medical applications, by qualified/trained doctors or technicians on both adult and pediatric patients for taking diagnostic radiographic exposures of body parts.

-The AJEX 9015H is used by foot and hand care clinics and portable orthopedic needs by sports medicine groups at sports arenas for general radiographic exposures.

-The AJEX 135H is used in general radiographic mobile applications with stand, by qualified/trained doctors, technicians or nurses, for on –site and off-site patients that are not mobile .

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _N/A____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052341