K122697

OCT 5 2012

510(k) Summary

510(k) Submitter:

JOB Corporation
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Date Prepared: August 16, 2012
Contact: Hiroya Obana, Senior Manager

Trade/Proprietary name: PORTA 100HF
Common/usual name: Portable general purpose diagnostic X-ray unit
Classification name: Mobile X-ray system, Product Code IZL

Equivalent Legally Marketed Device:
This product is similar in function to the Mikasa X-Ray Co., LTD.'s MinXray HF100H+ (K052721.)

Intended Use:
PORTA 100HF is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.

Description of the Device:
PORTA 100HF is an X-ray unit which operates from AC100-120V/15A or AC200-240V/10A. The device consists of the control panel with the kV and mAs selectors (a rotary switch system) and display for radiographic operations, and the APR switch with 8 memory settings (kV/mAs) to store the exposure data. The device also consists of the X-ray tube, the collimator, power code, and the hand switch, comprising the mono-tank type of a portable X-ray unit. The unit utilizes a high frequency inverter designed to be mounted on a stand. The device can be used with conventional X-ray film or digital imaging media. The usual safety precautions regarding X-rays must be observed by the operator.

Nonclinical Tests for a Determination of Substantial Equivalence:
PORTA 100HF has been tested for electrical safety and electromagnetic compatibility (IEC 60601-1-2, CISPR11, IEC 60601-2-7, IEC 60601-2-54, IEC 60601-1-3, IEC 60601-2-28, and IEC 60601-1:2005.) The device also complies with Underwriters Laboratories Standards for Safety (UL2601-1.) The software validation and verification testing was also performed. The results of nonclinical testing indicate that the PORTA 100HF is as safe and effective as the predicate device.

Substantial Equivalence Chart:

Characteristics	(Mikasa X-Ray Co., LTD.) MinXray HF 100H+ (K052721)	(JOB Corporation) PORTA 100HF
Intended Use	Intended use by a qualified/technician on both adult and pediatric subjects for taking diagnostic X-rays	Same
Physical Characteristics		
Size/weight	406mmx222mmx241mm 18.6Kgs	160mmx161mmx291mm 9.2Kgs
Energy Source (Input Voltage)	AC100-140V or AC200-260V	AC100-120V/15A or AC200-240V/10A
Mounting Method	Unit is usually mounted to MinXray XGS MKIII portable stand	Unit is mounted to a commercially available portable stand
Technical Characteristics		
User Interface	Up-down pushbottons for kVp selections and exposure time selections with LED indicators and mAs indicators	Up and down Rotary switch for kV and mAs value with 7 segment LED
Exposure times	0.03-2.00 sec. 0.01 increments	0.01-2.50 second 32 steps
Exposure switch	Dual-stage deadman type	Dual stage, deadman type with curled cable.
Controls	Software based	Software based
Construction	Monobloc HF generator, Medical full bridge inverter system	Monobloc HF generator, Medical full bridge inverter system
High Voltage Adjustment	High frequency (60kHz) inverter	High frequency inverter
Line Voltage Adjustment	Automatic, dynamic	Automatic, dynamic
Tube Potential (kV)	40-100kV (2kVstep)	40-100kV (2kV step).
kV step	31(2kV-step)	31(2kV-step)
Tube current	30mA (40-60kV) 25mA (62-80kV) 20mA (82-100kV)	30mA (40-66kV) 20mA (68kV-100kV)
X-ray tube	Toshiba D-124S	Toshiba D-124
Anode heat Storage	20,000HU	20,000HU
Focal Spot Size	1.2mm	1.2mm
mAs	0.6-120mAs	0.3mAs-50mAs
Total Filtration	3.2mm AL equivalent	2.5mm AL. eq. at 100kV

Collimator	Continuously adjustable (30 sec.) light beam type with central X-ray indicator	Complete with 30 sec. timer and cross indication line.
Source to Skin Distance (SSD)	300mm	216mm
KvP	100KvP	100KvP
Performance Standard	21CFR 1020.30 UL 2601	21CFR 1020.30 UL 2601-1
Electrical Safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1:2005 IEC 60601-1-3 IEC 60601-2-28 IEC 60601-1-2 CISPR11 IEC 60601-2-7 IEC 60601-2-54
X-ray Radiography	Conventional X-ray film or digital imaging media	Conventional X-ray film or digital imaging media

Conclusion:

The PORTA 100HF is intended for the same indications for use as the predicate device and the results of the nonclinical testing demonstrate that the PORTA 100HF is as safe and effective as the predicate device. It is the conclusion of JOB Corporation that the PORTA 100HF is as safe and effective as the predicate device and has few technological differences, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 5 2012

JOB Corporation
% Mr. Takahiro Haruyama
President
Globizz Corporation
1411 West 190th Street, Suite 120
GARDENA CA 90248

Re: K122697
Trade/Device Name: PORTA 100HF
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: IZL
Dated: August 27, 2012
Received: September 4, 2012

Dear Mr. Haruyama:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: PORTA 100HF

Indications for Use:

PORTA 100HF is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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