



Food and Drug Administration
10903 New Hampshire Avenue
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OSKO, INC.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

May 7, 2015

Re: K150663
Trade/Device Name: XR5 Diagnostic X-ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: March 13, 2015
Received: March 16, 2015

Dear Mr. Kim:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150663

Device Name

XR5 Diagnostic X-ray System

Indications for Use (Describe)

The XR5 diagnostic X-ray system is intended for use on adult and pediatric patients for taking diagnostics radiographic exposure of all body parts and operated by a qualified/trained doctor or technician. The XR5 diagnostic X-ray system is designed to be used with conventional film/screen, CR cassettes or digital detectors. NOT intended for Mammography use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: May 1, 2015

Submitter's Name, address, telephone number, a contact person:

1. Submitter OSKO, Inc.
7260 NW 58th Street, Miami, Florida 33166, USA
www.oskomedical.com
2. Contact Person Name: Wang Choi
Position: Vice President
E-mail: bioking@medisoneconet.com
Telephone: + 1 305-599-7161

Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

3. Regulation Name Stationary X-ray System
4. Device Name XR5
5. Classification 21 CFR 892.1680
6. Product Code KPR
7. Device Class 2
8. Predicate Device Multix Fusion by Siemens Medical Solutions USA, Inc
K121513 (Decision Date – Aug 10, 2012)
Stationary X-ray System
21CFR892.1680
KPR



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9. Device Description

The XR5 diagnostic X-ray system is used for image capture by using X-rays on a patient's body. The XR5 is a conventional X-ray machine, with an intuitive operation console to provide the user an easy way to manage optimal conditions for quality images. The high frequency generator is capable of delivering the exposition dose appropriate for general X-ray and diagnostic images of a patient. This system is made to use other detector options including; conventional films, CR, or Digital Flat Panel Detectors. Please note that the quality of the image in any detector depends on the manufacture of the receptor device. The XR5 diagnostic X-ray system doesn't provide an AEC feature.

10. Indications for Use

The XR5 diagnostic X-ray system is intended for use on adult and pediatric patients for taking diagnostics radiographic exposure of all body parts and operated by a qualified/trained doctor or technician. The XR5 diagnostic X-ray system is designed to be used with conventional film/screen, CR cassettes or digital detectors. NOT intended for Mammography use.

11. Specifications of Device

11.1 System Environment Requirement

a) ENVIRONMENTAL SPECIFICATIONS

OPERATING

Ambient temperature range	10 to 40 °C (50 to 104 °F).
Relative humidity	20 to 80%, non-condensing.
Altitude	-700 to 3000 meters (1100 to 700 hPa, 825 to 525 mm Hg).

Electrical Requirement

<i>System Part</i>	<i>Specifications</i>
<i>Generator</i>	220 ~ 240 VAC monophasic, 50/60 Hz @ 40kW
<i>Mechanical Part</i>	110~220VAC



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11.2 Movement Specifications

Required power : 24V, 3A

Tube stand height : 1,940 mm / 73"

SID range : 1,000 ~ 1,800 mm / 39" ~ 70"

Vertical movement : 1,480 mm / 58"

Longitudinal movement : 2,540 mm / 100"

Tube rotation range : -135° ~ +135°

Forward/backward tube head range : ± 120 mm / ± 4.7 "

11.3 Patient Table Specifications

Type : 4-Way floating table

Dimensions : 220 X 806 X 728 X 655 mm / 9" x 32" x 29" x 26" (Rounded to nearest inch)

Backward/forward movement : ± 105 mm / ± 4.1 "

Left/right Movement: ± 450 mm / ± 18 "

Patient Weight Limit: Patient Weight(215 kg) + Accessory Weight(15kg) / Patient Weight(473lb) + Accessory Weight (33lb)

11.4 Collimator Specifications

Type : Manual

Power Output : DC 24V

Projecting lamp : 150W Halogen lamp

Lighting type : Automatic illumination

Lighting time: press button, 30 sec

APR memory : No

Laser guide : No

Max. window : 48 x 48 cm (SID 100 cm) / 19"x 19" (SID 39")

Min. window : 5 X 5 cm (SID 100 cm) / 2"x 2" (SID 39")

11.5 X-ray Tube Specifications

Model : E7239x

Focal Spot : 1.0 / 2.0 mm

Operation Voltage : 40 ~ 125 kVp

Target angle : 16°

Composition of the target : Rhenium – Tungsten faced molybdenum

Permanent filtration : 0.9mmAl/75kV

Anode Heat capacity : 140 KHU

Additional Filter : 1.5mmAl

Target : rhenium-tungsten-faced molybdenum

Permanent filtration : 0.9mm Al at 75 kV

Cooling method : Natural / Forced air

Operation Temp. : 10 ~ 40°C / 50 ~ 104°F

Operation Hum. : 30 ~ 85%

11.6 Grid Specifications



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Composition : interspaced carbon with carbon fiber cover

Dimensions : 46 x 46,8 cm / 18"x 18"x 3"

Density : 103 lp/cm

Ratio : 10:1

FID : 100 and 180 cm / 39" and 71"

12. HF Generator Specifications

OUTPUT PARAMETER	GENERATOR SERIES	LOADING FACTOR
Maximum X-ray tube voltage and highest X-ray tube current at that voltage	40 kW	125 kV, 320 mA / 150 kV, 250 mA
Maximum X-ray tube current and highest X-ray tube voltage at that current	40 kW	500 mA, 80 kV
Combination of X-ray tube current and X-ray tube voltage resulting in highest output power	40 kW	400 mA, 100 kV
Highest constant output power at 100 kV, 0.1 sec	40 kW	40 kW (400 mA, 100 kV, 0.1 s)

13. Summary of the Technological Characteristics of the device compared to the Predicate Device

The XR5 diagnostic X-ray system described in this 501K has the similar indications for use and technical characteristics as the predicate device, Multix Fusion of Siemens Medical Solution USA, Inc. (K121513)

Feature	New Device: XR5 Product Code: KPR	Predicate: Multix Fusion (K121513) Product Code: KPR
Manufacturer	OSKO, Inc	Siemens Medical Solution USA, Inc
Indications for Use	The XR5 diagnostic X-ray system is intended for use on adult and pediatric patients for taking diagnostics radiographic exposure of all body parts and operated by a qualified/trained doctor or technician. The XR5 diagnostic X-ray system is designed to be used with conventional	The Multix Fusion system is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position.



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	film/screen, CR cassettes or digital detectors. NOT intended for Mammography use.	The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile (wired) or portable (wireless) digital detector for generating diagnostic images by converting x-rays into electronic signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.
Configuration	Patient sitting, standing, in the prone position	Patient sitting, standing, in the prone position
Performance Standard	21 CFR 1020.30	21 CFR 1020.30
Generator	High frequency	High frequency
Collimator	Manual (K062788)	ACSS collimator (Automatic Cassette Size Sensing)
Image acquisition	Film/Screen, CR Cassettes, or digital flat panel detectors	Film/Screen, CR Cassettes, or digital flat panel detector
Flat Panel Detector	1717SCC(K122173): 43cm x 43 cm 1417WCC (K141566): 43 cm x 36cm FLAATZ600 (K132842): 43cm x 36cm	43cm X 36cm (4336X)
Imaging Software	By default, XR5 does not provide the imaging software with image processing features. Separate imaging software with a FDA clearance is available for the user provided by the manufacturer of the detector of choice; FEEL-DRCS (K110033) for FLAATZ 600 (K132842) and XmaruView V1(K102078) for 1417 WCC (K141566) and 1717SCC (K122173).	

14. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device:

The XR5 diagnostic X-ray system does not have significant changes in energy source, or technological characteristics when compared to the predicate device. It uses the components similar to the predicate device (tube, generator, floor anchored tube support, table, bucky wall stand). The indications for use and fundamental scientific technology are similar to the predicate device, with the exception of bariatric patients and tomography application.

The main differences are the digital detectors used for XR5 X-ray system. However, the fundamental imaging technology is the same. The safety and effectiveness of the



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digital detectors for XR5 have been reviewed and cleared by FDA as indicated by the 510K number of each detector.

1717SCC (K122173)
1417WCC (K141566)
FLAATZ600 (K132842)

By default, XR5 does not provide the imaging software with image processing features. Separate imaging software with a FDA clearance is available for the user provided by the manufacturer of the detector of choice; FEEL-DRCS (K110033) for FLAATZ 600 (K132842) and XmaruView V1(K102078) for 1417 WCC (K141566) and 1717SCC (K122173).

15. Summary of Software Validation

XR5 firmware is a software embedded device programmed with ANSI C language. It controls the hardware operating module to run the equipment and synchronize the positions of the X-ray tube and buck according to the patient's position. It also displays information necessary for taking an X-ray image including SID.

The complete system configuration including the firmware function has been assessed and tested by the manufacturer and passed all in-house testing criteria. The firmware validation test was designed to evaluate for the X-ray system including X-ray exposure control and exposure switch performed by XR5.

The level of concern is moderate and the firmware is not based on any predicate device. The validation testing verified and validated the risk analysis and individual performance results were within the predetermined acceptance criteria.

Both subject device and predicate device are categorized in product code KPR ; equivalence between these models is evident.

In conclusion, the XR5 is substantially equivalent to predicate devices.

16. Summary of Non-Clinical Testing

The detectors listed have been cleared by FDA's 510(k) process. The detector performance parameters including DQE and MTF are evaluated according to IEC 62220-1:2003 Standard to demonstrate the safety and effectiveness performance. MTF of 1717SCC (K122173) and 1417 WCC (K141566) and FLAATZ600 (K132842) are 13%, 12.1% and 50.02%, respectively at 3.5 lp/mm.

DQE of 1717SCC (K122173) and 1417 WCC (K141566) and FLAATZ600 (K132842) are 54%, 76.7% and 50%, respectively at 0 spatial frequency.

The line resolution of 1717SCC (K122173) and 1417 WCC (K141566) and FLAATZ600 (K132842) are similar between 3.0~3.5 lp/mm.

The risk analysis is performed to identify additional hazards, conduct risk mitigation measures and evaluate the acceptance criteria for residual risks.



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17. Summary of Clinical Testing

Bench performance parameters for the digital detectors are sufficient to demonstrate substantial equivalence to a predicate device. While the sample clinical images may be helpful for demonstrating the clinical use of your device and that it performs adequately in the general use radiographic imaging for which your device is indicated, bench performance data should be sufficient for determining substantial equivalence. Clinical images are not necessary to establish substantial equivalence based on the previously FDA cleared detectors.

18. Functional and Safety Testing

The XR5 diagnostic X-ray system has been tested in accordance with Safety standard of IEC 60601-1; 2005 + A1 (2012) and IEC 60601-2-54; Edition 1.0.2009. The test reports have shown good performance, substantially equivalent to the predicate device.

The XR5 has also met applicable Electro Magnetic Compatibility (EMC) requirements; EN60601-1-2:2007 / AC : 2010 (IEC60601-1-2:2007).

19. Conclusion

The XR5 diagnostic X-ray system is intended for the similar use as Multix Fusion (with the exception of bariatric patients and tomography application). It uses similar components cleared for the Multix Fusion (e.g. tube, generator, ceiling-mounted tube support, table, bucky wall stand). The XR5 is substantially equivalent to the already cleared predicate device.