DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 6, 2017

OSKO, INC.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K172681
Trade/Device Name: Edge Air Digital Flat Panel X-ray Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 29, 2017
Received: September 6, 2017

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,


For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K172681

Device Name
Edge Air
Digital Flat Panel X-ray Detector

Indications for Use *(Describe)*

Edge Air Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general purpose diagnostic procedures. Not to be used for mammography.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**1. Traditional 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:** September 29, 2017

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

| | |
|---|---|
| **Submitter's Name:** | OSKO, Inc. |
| **Submitter's Address:** | 8085 NW 90th Street, Miami, Florida 33166, USA |
| **Submitter's Telephone:** | +1-305-599-7161 |
| **Contact Person:** | Ms. Vivian Garcia / RA Manager / +1-305-599-7161 |
| **Official Correspondent:** | Dave Kim (davekim@mtech-inc.net) **(U.S. Agent)** |
| **Address:** | 8310 Buffalo Speedway, Houston, TX 77025 |
| **Telephone:** | +713-467-2607 |
| **Fax:** | +713-583-8988 |

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

| | |
|---|---|
| **Trade/Proprietary name:** | Edge Air |
| **Common Name:** | Digital Flat Panel X-ray Detector |
| **Classification Name:** | 21CFR892.1680 / Stationary x-ray system |
| **Product Code:** | MQB |
| **Product Classification:** | Class II |

| | |
|---|---|
| **Predicate Device:** | |
| **Manufacturer:** | Rayence Co., Ltd. |
| **Device:** | 1717WCC |
| **510(k) Number:** | K162519 |
| **Classification Name:** | 21CFR892.1680 / Stationary x-ray system |
| **Product Code:** | MQB (Class II) |

## 2. Device Description

Edge Air is a wired/wireless digital solid state X-ray detector that is based on flat-panel technology. The wireless LAN (IEEE 802.11a/g/n/ac) communication signals images captured to the system and improves the user operability through high-speed processing. This radiographic image detector and processing unit consists of a scintillator coupled to an a-Si TFT sensor. This device needs to be integrated with a radiographic imaging system. It can be utilized to capture and digitalize X-ray images for radiographic diagnosis The RAW files can be further processed as DICOM compatible image files by a separate console SW program (K160579 / Xmaru View V1 and Xmaru PACS/ Rayence Co., Ltd.) for a diagnostic analysis.

## 3. Intended Use

Edge Air Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. Not to be used for mammography.

## 4. Summary of Design Control Risk Management

The Edge Air Digital Flat Panel X-Ray Detector is developed for the purpose of portable imaging. The risk and the hazardous impact of the device modification were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design change were successfully mitigated and accepted.

The Edge Air Digital Flat Panel Detector uses the same flat panel x-ray detector as that used in the predicate device, K162519, and that no changes were necessary to either the hardware or firmware of the device.

## 5. Summary of the technological characteristics of the device compared to the predicated device:

The Edge Air detector described in this 510(k) has the same indications for use and similar technical characteristics as the predicate devices, 1717WCC of Rayence Co., Ltd

The Edge Air detector described in this 510(k) uses the same hardware, firmware and the same version of imaging software Xmaru View 1 / Xmaru PACS (K160579), without any change, that are used by the predicate device, 1717WCC.

Xmaru View 1 FDA 510(k) information is as follows:

| Item | Device Classification Name | Device name | 510(k) number | Applicant |
|---|---|---|---|---|
| FDA 510(k) | System, Image Processing, Radiological | Xmaru View V1 and Xmaru PACS, Medical image processing software | K160579 | Rayence Co., Ltd. |

**5.1 Comparison Table**

| Characteristic | Proposed<br>OSKO, INC.<br>Edge Air | Predicate<br>Rayence Co., Ltd.<br>1717WCC | |
|---|---|---|---|
| ***Feature*** |  |  | |
| ***510(k) number*** | K176281 | K162519 | |
| Intended Use | Edge Air Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. Not to be used for mammography. | 1717WCC Digital Flat Panel X-Ray Detectors are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. Not to be used for mammography. | Same |
| ***Detector Type*** | Amorphous Silicon, TFT | Amorphous Silicon, TFT | Same |
| ***Scintillator*** | CsI:T1 | CsI:T1 | Same |
| ***Imaging Area*** | 17 x 17 inches | 17 x 17 inches | Same |
| ***Pixel Matrix*** | 3072 X 3072 | 139, 140 : 3072 X 3072 | Same |
| ***Pixel Pitch*** | 140 µm | 140 µm | Same |

| | | | |
|---|---|---|---|
| ***Resolution*** | 3.9 lp/mm | 3.9 lp/mm | Same |
| ***A/D Conversion*** | 14 / 16 bit | 14 / 16 bit | Same |
| ***Preview Time*** | ≤2 | ≤2 | Same |
| ***MTF (@1lp/mm)*** | 58 (%)<br>*Result value from Non-Clinical Report | 56 (%) | Similar |
| ***DQE (@0.1lp/mm)*** | 77.5 (%)<br>* Result value from Non-Clinical Report | 80 (%) | Similar |
| ***Data Output*** | RAW<br>*The RAW files are convertible into DICOM 3.0 by console S/W | RAW<br>*The RAW files are convertible into DICOM 3.0 by console S/W | Same |
| ***Imaging Software*** | Xmaru View 1 / Xmaru PACS (Version 2.0.0) | Xmaru View 1 / Xmaru PACS (Version 2.0.0) | Same |
| ***Wireless Specifications*** | -Standard: 802.11 a/g/n/ac compliance Without DFS (5.25GH to 5.35GHzand 5.47 to 5.725) Band<br>-Peak Rate:1300Mbps<br>-Frequency: 2.4 GHz / 5 GHz<br>-Bandwith: 20MHz / 40MHz / 80MHz<br>-MIMO: 3 x 3 | -Standard: 802.11 a/g/n/ac compliance Without DFS (5.25GH to 5.35GHzand 5.47 to 5.725) Band<br>-Peak Rate:1300Mbps<br>-Frequency: 2.4 GHz / 5 GHz<br>-Bandwith: 20MHz / 40MHz / 80MHz<br>-MIMO: 3 x 3 | Same |
| ***Dimensions*** | 460 × 460 × 15 mm | 460 × 460 × 15 mm | Same |
| ***Weight*** | 3.5 kg (incl. battery) | 3.5 kg (incl. battery) | Same |
| ***Application*** | General Radiology system or Wireless/Wired portable system Available with upright stand, table, universal stand | General Radiology system or Wireless/Wired portable system Available with upright stand, table, universal stand | Same |
| ***Added Optional Components*** | Battery & Battery Charger Interface Cox IrDA module | Battery & Battery Charger Interface Cox IrDA module | Same |

- The Edge Air Digital Flat Panel Detector is identical to the wireless hardware and functionality of the predicate device, 1717WCC.

  Maximum wireless signal rate derived from IEEE standard specifications. Actual data throughput will vary. Network conditions and environmental factors, including volume of network traffic, building materials and construction, and network overhead, lower actual data throughput rate.

### 5.2 Scintillator Layer

The scintillator (*a phosphor that produces scintillations*) layer of the Edge Air detector is described as below.

| | Proposed | Predicate |
|---|---|---|
| CsI<br>(Cesium Iodide) | Edge Air | 1717WCC |

### 5.3 Added Optional Components

| Components | Description |
|---|---|
| **Battery & Battery Charger**  | Sources of electricity |
| **Mobile Battery Charger**  | |
| **Interface Box**  | 1) Connector to synchronize the detector and its generator.<br>2) Data transfer and battery charge while the detector is in use (Connect between the detector and Interface Box), Up to three detectors can be connected.<br>3) Transmitting an image/command between the detector and PC.<br>4) Wireless AP. |
| **IrDA module**  | Sharing function for PC and the detector. |

### 5.4 Recommended Generator Specification

| Model | Manufacture | Specification | | | |
|---|---|---|---|---|---|
| CMP 200 | Communications & Power Industries | | 32kW | 40kW | 50kW |
| | | kVp | 40-125 | | 40-150 |

| | | | | | |
|---|---|---|---|---|---|
| | | mA | 10-400 | 10-500 | 10-630 |
| EDITOR HFe 501 | Rontgenwerk Bochum | kVp | 40-150 | | |
| | | mA | 10-630 | | |
| UD150L-40E/40F | Shimadzu | kVp | 40-150 | | |
| | | mA | @100 kVp- 500(320) | | |
| | | | @80 kVp- 630(400) | | |
| PXR-321B | POSKO, m Co.,Ltd. | kVp | 125/150 | | |
| | | mA | 500 | | |

**CAUTION**

- **To our best knowledge, the detector is compatible with the X-ray generators with the specifications described above.**
- **If you have questions regarding the compatibility issue for other generators which are not listed above, please contact your OSKO, Inc. representative.**

**6. Summary of Performance Testing compared with predicate device**

The Edge Air Digital Flat Panel X-Ray Detector has the same indications for use, material, form factor, performance, and safety characteristics compared to the predicate device, 1717WCC.
The non-clinical test and clinical consideration test for the Edge Air have been performed to demonstrate the substantial equivalency of the subject devices compared to the predicate device, 1717WCC. The non-clinical test report contains the MTF, DQE and NPS test results of Edge Air by using the identical test equipment and same analysis method described by IEC 62220-1.

The comparative result of the MTF and DQE test for Edge Air detector with respect to the predicate demonstrated that the MTF and DQE of the subject devices performed same with the predicate device, 1717WCC. The MTF and DQE represent the ability to visualize object details of a certain size and contrast. The comparable performance of the MTF and DQE for the Edge Air detector demonstrated that the performed almost same with 1717WCC.

To further demonstrate the substantial equivalency of the Edge Air, clinical images have been reviewed by a licensed radiologist to render an expert opinion. The test subject (Edge Air) and the predicate device (1717WCC) have been evaluated and compared by talking sample radiographs of similar age group and anatomical structures in accordance with the test protocol of diagnostic radiography evaluation procedure.

After a broad review of plain radiographic images taken with the Edge Air, the image obtained with the Edge Air is similar to the same view obtained from a similar patient with the predicate device, 1717WCC. In general, the spatial and soft tissue contrast resolutions for both devices are equivalent. Specially, the soft tissues on extremity films were seen with better clarity.
Based on the non-clinical and clinical consideration test and the outcome of a comparative review by an expert for the Edge Air, the sponsor can claim the substantial equivalency between the subject device and the predicate device in terms of diagnostic image quality.

The manufacturing facility is in conformance with the design control procedure requirements and the relevant EPRC standards as specified in 21 CFR 802.30 and the records are available for review.

Note: *Clinical images were provided; even though these images are not necessary to establish substantial equivalence based on the modifications to the device, they provide additional evidence in addition to bench testing data to show that the complete system works as intended.*

**7. Summary for any testing in the submission:**
Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1:2005 (3rd Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance) was performed, and EMC testing were conducted in accordance with standard IEC 60601-1-2:2007.

The Non-clinical consideration & performance test have been conducted according to the following FDA Guidance.

- Performance Standards for Ionizing Radiation Emitting Products, 21 CFR 1020
- Diagnostic x-ray systems and their major components, 21 CFR 1020.30
- Radiographic Equipment, 21 CFR 1020.31
- FDA Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices
- FDA Guidance titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"

All test results were satisfactory.

**8. Conclusion:**
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification OSKO, INC. concludes that Edge Air is substantially equivalent in comparison with 1717WCC, the predicate device as described herein.