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: K172682
Trade/Device Name: Edge 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)*

K172682

Device Name
Edge
Digital Flat Panel X-ray Detector

Indications for Use *(Describe)*

Edge 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.

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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:	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**:**	+713-464-8880

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
Common Name	: Digital Flat Panel X-ray Detector
Classification Name	: 21CFR892.1680 / Stationary x-ray system
Product Code	: MQB
Classification	: Class II

Predicate Device :

Manufacturer	: Rayence Co., Ltd
Device	: 1717SCC_140μm
510(k) Number	: K171420
Classification Name	: 21CFR892.1680 / Stationary x-ray system
Product Code	: MQB

2. **Device Description :**

Edge digital flat panel X-ray detector is based on flat-panel technology. 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 separate console SW (K160579 / XmaruView V1 and XmaruPACS/ Rayence Co.,Ltd.) for a radiographic diagnosis and analysis.

3. **Indication for use** :

Edge is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.

4. **Summary of the Design Control Risk Management**:

The Edge digital X-ray detector is a modification of 1717SCC_140 μm (K171420) which was developed for the purpose of retrofitting the stationary a film X-ray system. Edge is connected to a PC with an ethernet cable.

The risks 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 digital solid state X-ray detector uses the same panel and components that the predicate device, 1717SCC_140 μm (K171420) and that no changes were necessary to eiter the hardware or firmware of the device.

5. **Summary of the technological characteristics of the device compared to the predicate device:**

The Edge digital solid state X-ray detector described in this 510(k) has the same indications for use and similar technical characteristics as its predicate device, 1717SCC_140 μm (K171420) flat panel detector, of Rayence Co., Ltd

The Edge digital solid state X-ray detector described in this 510(k) uses the same hardware, firmware and imaging software Xmaru View 1 and Xmaru PACS (K160579), without any change, that are used by the predicate device, 1717SCC_140 μm.

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 Scintillator layer

**scintillator* layer. (** scintillator : a phosphor that produces scintillations*)

	Proposed	Predicate
CsI (Cesium Iodide)	Edge	1717SCC_140 μm

5.2 Dimensions and Weight

		Proposed Edge	Predicate 1717SCC_140 μm
Detector	Model name	Edge	1717SCC_140μm
	W x L x H	460 X 460 X 15.5	460 X 460 X 15.5
	Weight	4 kg	4 kg
Power supply	Model name	RS1717	RS1717
	W x L x H	188 X 92 X 41.5	188 X 92 X 41.5
	Weight	0.5 kg	0.5 kg

5.3 Power Requirements (Power supply)

		Proposed Edge	Predicate 1717SCC_140 μm
Power supply	Model name	RS1717	RS1717
	W x L x H	AC 100 - 240 V~, 50/60Hz	AC 100 - 240 V~, 50/60Hz

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	Poskom 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 Rayence representative.**

This information will be included in user/installation documents for the end user.

5.5 Comparison table

Characteristic	Proposed Edge	Predicate 1717SCC_140 μm	Remarks
510(k) number	K172682	K171420	
Intended Use	Edge X-ray detectors, 140um, are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.	1717SCC_127um and 1717SCC_140um, are indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography.	Same
Manufacturer	OSKO, INC.	Rayence Co., Ltd.	

Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT	Same
Scintillator	CsI:Tl	CsI:Tl	Same
Imaging Area	17 x 17 inches	140 type : 3072 x 3072	Same
Pixel matrix	3072 x 3072	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)	59.1 (%)	58.2 (%)	Similar
DQE	76 (%) *Result value from Non-Clinical Report	74 (%) *Result value from Non-Clinical Report	Similar
Data output	RAW *The RAW files are convertible into DICOM 3.0 by console S/W	RAW *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
Dimensions	460 × 460 × 15.5 mm	460 × 460 × 15.5 mm	Same
Weight	4 kg	4 kg	Same
Application	General Radiology system or Portable system Available with upright stand, table, universal stand.	General Radiology system or Portable system Available with upright stand, table, universal stand.	Same

- The Edge Digital Flat Panel Detector is identical to the wireless hardware and functionality of the predicate device, 1717SCC_140 µm.

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.

6. Summary of Performance Testing:

The Edge Digital Flat Panel X-Ray Detector has the same indications for use, material, form factor, performance, and safety characteristics compared to the predicate devices, 1717SCC_140 µm (K171420) respectively.

The non-clinical test report and clinical consideration report for each subject device were prepared and submitted to FDA separately to demonstrate the substantial equivalency of the subject devices compared to each respective predicate device. The non-clinical test report contains the MTF, DQE and NPS test results of Edge 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 detector with respect to each respective predicate demonstrated that the MTF and DQE of the subject device performed similarly compared with the predicate device. The MTF and DQE represents the ability to visualize object details of a certain size and contrast. Edge has similar MTF and DQE performance at all spatial frequencies. The comparison of the MTF and DQE for Edge detector demonstrated that it performed almost same 1717SCC_140 µm (K171420).

To further demonstrate the substantial equivalency of two devices, clinical images are taken from both subject devices and reviewed by a licensed US radiologist to render an expert opinion. Both the test subject (Edge) and the predicate device (1717SCC_140 µm (K171420)) have been evaluated and compared by taking 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 Edge, the images obtained with Edge are superior to the same view obtained from a similar patient with the predicate devices, 1717SCC_140 µm (K171420). In general, both the spatial and soft tissue contrast resolution are superior using Edge. Specifically, 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 both devices, the sponsor can claim the substantial equivalency between the subject devices and their predicate devices 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. Conclusions :

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 is substantially equivalent in comparison with 1717SCC_140μm (K171420) the predicate device as described herein.