Osko, Inc.
℅ Mr. Hanmaru Chon
Regulatory Affairs Manager
8085 NW 90th Street
MIAMI FL 33166

June 29, 2020

Re: K201503
Trade/Device Name: Edge Air (1417) Digital Flat Panel X-ray Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: June 12, 2020
Received: June 12, 2020

Dear Mr. Chon:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201503

Device Name
Edge Air(1417) Digital Flat Panel X-Ray Detector

Indications for Use *(Describe)*
Edge Air(1417) 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.

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510(k) Submission Number: K201503

1. Special 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 29, 2020

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:	Mr. Hanmaru Chon / RA Manager / +1-305-599-7161
Official Correspondent:	Mr. Hanmaru Chon (hanmaru@oskomedical.com)
Address:	8085 NW 90th Street, Miami, Florida 33166, USA
Telephone:	+1 305-599-7161
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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 and Common Name:	Edge Air(1417) Digital Flat Panel X-Ray Detector
Classification Name:	21CFR892.1680 / Stationary x-ray system
Product Code:	MQB
Product Classification:	Class II

Predicate Device	
Manufacturer:	OSKO, INC.
Device:	Edge Air
510(k) Number:	K172681
Classification Name:	21CFR892.1680 / Stationary x-ray system
Product Code:	MQB (Class II)

2. Device Description

Edge Air(1417) 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 (K190866 / Xmaruview V1 (Xmaru Chiroview, Xmaru Podview) / Rayence Co., Ltd.) for a diagnostic analysis.

3. Intended Use

Edge Air(1417) 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(1417) 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(1417) Digital Flat Panel X-Ray Detector uses the same flat panel x-ray detector as that used in the predicate device Edge Air, K172681, 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(1417) detector described in this 510(k) has the same indications for use and similar technical characteristics as the predicate devices, Edge Air of OSKO, INC.

The Edge Air(1417) detector described in this 510(k) uses the same hardware, firmware and the same version of imaging software Xmaruview V1(K190866), without any change, that the predicate device Edge Air. The only difference from the predicate detector is a smaller size. All other technological characteristics are similar.

Xmaruview V1 FDA 510(k) information is as follows:

Item	Device Classification Name	Device name	510(k) number	Applicant
FDA 510(k)	System, Image Processing, Radiological	Xmaruview V1 (Xmaru Chiroview, Xmaru Podview)	K190866	Rayence Co., Ltd.

5.1 Comparison Table

Characteristic	Proposed OSKO, INC. Edge Air(1417)	Predicate OSKO, INC. Edge Air	
Feature			
510(k) number	-	K172681	
Intended Use	Edge Air(1417) 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.	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.	Same
Detector Type	Amorphous Silicon, TFT	Amorphous Silicon, TFT	Same
Scintillator	CsI:TI	CsI:TI	Same
Imaging Area	14 × 17 inches	17 × 17 inches	Similar
Pixel Matrix	2500 × 3052	3072 × 3072	Similar
Pixel Pitch	140 µm	140 µm	Same
Resolution	3.57 lp/mm	3.57 lp/mm	Same
A/D Conversion	14 / 16 bit	14 / 16 bit	Same
Preview Time	≤2	≤2	Same
MTF (@1lp/mm)	53.0 (%) *Result value from Non-Clinical Report	55.3 (%) *Result value from Non-Clinical Report	Similar

DQE (@0.1lp/mm)	75.1 (%) *Result value from Non-Clinical Report	74.4 (%) *Result value from Non-Clinical Report	Similar
NPS (@0.1lp/mm)	11.307 *Result value from Non-Clinical Report	6.875 *Result value from Non-Clinical Report	Similar
Data Output	DICOM 3.0	DICOM 3.0	Same
Imaging Software	Xmaruview V1	Xmaruview V1	Same
Wireless Specifications	-Standard: 802.11 a/g/n/ac compliance Without DFS (5.25GH to 5.35GHzand 5.47 to 5.725) Band -Peak Rate:1300Mbps -Frequency: 2.4 GHz / 5 GHz -Bandwith: 20MHz / 40MHz / 80MHz -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 -Peak Rate:1300Mbps -Frequency: 2.4 GHz / 5 GHz -Bandwith: 20MHz / 40MHz / 80MHz -MIMO: 3 x 3	Same
Dimensions	384 × 460 × 15 mm	460 × 460 × 15 mm	Similar
Weight	3.0 kg (incl. battery)	3.5 kg (incl. battery)	Similar
Application	General radiology system or portable system	General radiology system or portable system	Same
Added Optional Components	Battery & Battery Charger, Power Supply	Battery & Battery Charger, Power Supply, Interface Cox IrDA module	Similar

- The Edge Air(1417) Digital Flat Panel X-ray Detector is identical to the wireless hardware and functionality of the predicate device, Edge Air.
  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(1417) detector is described as below.

	Proposed	**Predicate**
CsI (Cesium Iodide)	Edge Air(1417)	Edge Air

5.3 Recommended Generator Specification

The subject detector Edge Air(1417) does not connect to the x-ray generator. The subject detector is compatible with any x-ray system operating at 40 to 150 KVp and 0.1 to 1000 mAs

6. Summary of Performance Testing compared with predicate device

The Edge Air(1417) Digital Flat Panel X-Ray Detector has the same indications for use, material, form factor, performance, and safety characteristics compared to the predicate device, Edge Air.

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, Edge Air. The non-clinical test report contains the MTF, DQE and NPS test results of Edge Air(1417) 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(1417) detector with respect to the predicate demonstrated that the MTF and DQE of the subject devices performed same with the predicate device, Edge Air. 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(1417) detector demonstrated that the performed almost same with Edge Air.

To further demonstrate the substantial equivalency of the Edge Air(1417), clinical images have been reviewed by a licensed radiologist to render an expert opinion. The test subject (Edge Air(1417)) and the predicate device (Edge Air) 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(1417), the image obtained with the Edge Air(1417) is similar to the same view obtained from a similar patient with the predicate device, Edge Air. 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(1417), 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(1417) is substantially equivalent in comparison with Edge Air, the predicate device as described herein.