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

January 7, 2016

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

Re: K150506
Trade/Device Name: Elian digital diagnostic x-ray system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: February 23, 2015
Received: February 26, 2015

Dear Mr. Kim:

This letter corrects our substantially equivalent letter of April 08, 2015.

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)*

Device Name

ELIAN Digital Diagnostic X-ray System

Indications for Use *(Describe)*

The ELIAN 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. 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.

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."

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: February 23, 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.	Device Classification Name	Stationary X-ray System
4.	Device Name	ELIAN Digital Diagnostic X-Ray System
5.	Classification	21 CFR 892.1680
6.	Product Code	KPR
7.	Device Class	2
8.	Predicate Device	Sedecal X-Plus LP Plus Digital Sedecal, Inc 892.1680, Product Code: KPR K090238 (Decision Date - Feb. 27. 2009) CXDI-50G CANON, Inc. 892.1680, Product Code: MQB K031447 (Decision Date – May, 21, 2003)

9. Device Description

The ELIAN is a digital radiographic image acquisition device. It is a fully integrated image capture and routing system under human operator control. This system may be usable by a technician in a typical radiology environment.

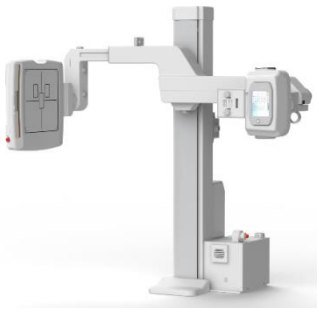
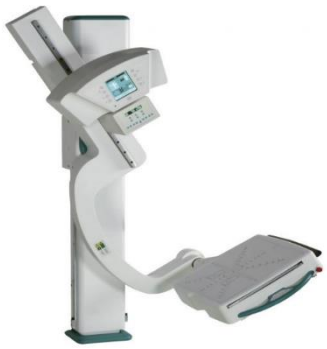
The ELIAN system includes a Detector Panel, Soft Ware, Case, Grid, Power Box, Switch Box, Interconnecting Cables, U-arm Mechanical and Generator. The Detector Panel is an indirect conversion device in the form of a rectangular plate in which the input x-ray photons are absorbed in an a-Si layer with CSI. The Power Box functions as a buffer between the Detector Panel and Operating PC while also supplying power to the Detector Panel. The Flugel SW transfers signals between the Detector and X-ray Generator and also indicates the status of the panel using console. Finally, the Flugel SW contains functions for image data capture and correction of defects on the image data.

10. Intended Use

The ELIAN 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. NOT intended for Mammography use.

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

The ELIAN digital diagnostic X-ray system described in this 501K has the similar indications for use and technical characteristics as the predicate device, Sedecal X-Plus LP Plus Digital of Sedecal, Inc. (K090238)

Feature	New Device: ELIAN Product Code: KPR	Predicate: (K090238) Sedecal X-Plus LP Plus Digital Product Code: KPR	Predicate: (K031447) CXDI 50G Product Code: MQB
Manufacturer	OSKO, Inc	Sedecal, Inc.	Canon Inc.
Appearances			

Intended Use	The ELIAN 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. NOT intended for Mammography use	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	The Canon digital radiography CXDI-50G is a portable X-ray digital camera that can take images of any part of the body. It directly converts the X-ray images captured by LANMIT (Large Area New MIS Sensors and TFT) sensor into a high-resolution digital images.
Configuration	U-Arm mount	U-Arm mount	-
Electrical safety	Electrical Safety per IEC-60601. UL listed.	Electrical Safety per IEC-60601. UL listed.	
Performance Standard	21 CFR 1020.30	21 CFR 1020.30	21 CFR 1020.30
Generator	High frequency	High frequency	-
X-ray tube	Toshiba (E7252X) used for the marketed device: K133782		
Collimator	Manual(Daesung)	Manual(Ralco) or Automatic (Huestis)	-
Image acquisition	Digital 1717SCC (K122173) -Type: Wired. Acquisition Software: flugel (Private label pro duct for XmaruView1, K102078)	Digital CANON CXDI Panels, mult iple models: 50C, 50G, 40C and 40G	CXDI-50G (K031447)
Detector Dimensions	17” x 17”		19.3” x 18.8”
MTF	0.49 (1lp/mm), 0.234 (2lp/mm), 0.11 (3lp/mm), 0.083(3.5lp/mm)		0.50 (1lp/mm), 0.22 (2lp/mm), 0.11 (3lp/mm)
DQE	DQE(0) – 0.22, DQE(1) – 0.35, DQE(2)-0.275, DQE(3)-0.14		DQE(0) – 0.1, DQE(1) – 0.25, DQE(2)-0.17, DQE(3)-0.09
Pixel Size	127 x 127 microns		160x160 microns
Dynamic Range	14 bits		12 bits
Spatial Resolution	3.5 lp/mm		3.1 lp/mm

12. Comparison discussion:

The model Sedecal X-Plus LP Plus Digital and CANON CXDI 50G are the primary predicate device. The subject device and predicate device are substantially equivalent, having the same intended use, configuration, electrical safety, performance standard, collimator and image acquisition. The differences are pixel size, dynamic range and spatial resolution only. Both subject device and predicate device are categorized in product code KPR ; equivalence between these models is evident.

There are similar characteristics between ELIAN and its predicate devices. The similarities ELIAN and the predicate device are listed below.

A few differences are as follows.
These differences do not raise any new questions of safety or effectiveness.

1. Differences in Dimensions
Dimensions of 1717SCC is 17X17" and that of CXDI-5 0G is 19.3X18.8". But it has no effect on efficiency and safety.
2. Differences in Pixel size
Pixel size of 1717SCC is 127 x 127 microns and that of CXDI-50G is 160 x 160 microns. But it has no effect on efficiency and safety.
3. Differences in Spatial Resolution
Spatial Resolution of 1717SCC is 3.5 lp/mm and that of CXDI-50G is 3.1 lp/mm. But it has no effect on efficiency and safety.
4. Differences in Non Clinical Performance
The MTF and DQE performance of the 1717 SCC digital flat panel for ELIAN are consistently higher than CDXI-50G equipped by Sedecal X-Plus LP Plus Digital.
In summary, both detectors are similar in terms of the capacity of transferring the modulation of the input signal at a given spatial frequency to its output, a useful measure of true or effective resolution.
Higher DQE values of 1717SCC, compared to CDXI-50G, indicate that less radiation is needed to achieve identical image quality; increasing the DQE and leaving radiation exposure constant will improve image quality.
5. Different image viewing software
1717SCC digital flat panel is compatible with the imaging software. The software used with the submitted device is 'flugel' and it is identical to the XmaruView V1., cleared under K102078.

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

13. Summary of Non-Clinical Testing

The performance of Detector can be evaluated by DQE and MTF according to IEC 62220-1:2003 Standard. DQE & MTF have been tested by acquiring the X-ray image with designated devices.
The overall test results conclude that ELIAN has outperformed the predicate device Sedecal X-Plus LP Plus Digital (K090238) in terms of modulation transfer function and detective quantum efficiency.

Moreover, ELIAN has been tested in accordance with Safety (IEC 60601-1; 2005 + A1 (2012)), EMC (EN60601-1-2:2007 / AC : 2010 (IEC60601-1-2:2007)), IEC 60601-2-54 (First Edition) : 2009 and DICOM standards (NEMA PS 3.1-3.20:2011).

14. Summary of Clinical Testing

Clinical study is to investigate the diagnostic equivalency of detector panels with the same a-Se technology and same pixel sizes. We've tested for eight body parts (Chest, Shoulder, L-Spine_L, L-Spine_AP, Hand, Forearm, Foot and Knee) compared to the predicate device. The result of tests demonstrated that ELIAN produces diagnostic images of equivalent quality as the predicate device Sedecal X-Plus LP Plus Digital of Sedecal, Inc. (K090238).

"Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended."

15. Functional and Safety Testing

The ELIAN has been evaluated as per FDA's "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices" and has shown good performance, substantially equivalent to the predicate device.

The ELIAN has also met applicable Electro Magnetic Compatibility (EMC) requirements.

16. Conclusion

The ELIAN is substantially equivalent to the Predicate Device in design and performance.

17. Manufacturing Facility

OSKO, INC.
7260 NW 58th Street, Miami, Florida, 33166 USA
Establishment Registration Number: 301066640