Skanray Technologies Private Limited
% Parul Chansoria
Regulatory Consultant
Elexes Medical Consulting Pvt Ltd.
#6494, Tralee Village Dr.
Dr Dublin, California 94568

November 24, 2017

Re: K170946
Trade/Device Name: Skan C Mobile C-Arm X-Ray system - 230V Variant (303-000187-1),
Skan C Mobile C-Arm X-Ray system - 110V Variant (303-000187-2)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OXO, OWB
Dated: October 17, 2017
Received: November 9, 2017

Dear Parul Chansoria:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170946

Device Name
Skan C Mobile C-Arm X-Ray system - 230V Variant (303-000187-1), Skan C Mobile C-Arm X-Ray system - 110V (303000187-2)

Indications for Use *(Describe)*
The Skan-C, a Mobile Surgical C-Arm X-Ray System, is intended to provide Fluoroscopic and Radiographic images of the patient during Diagnostic, Surgical and Interventional procedures.

Examples of Clinical Applications may include Orthopaedic, GI Procedure like Endoscopy and Cholenography, Neurology, Urology Procedures, Vascular, Critical Care and Emergency Room Procedures.

Skan-C is not recommended for Cardiac Applications.

Skan-C Surgical C-Arm is indicated for visualization in real time and/or recording of surgical region of interest and anatomy, using X-ray imaging technique.

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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1 Section.5- 510K Summary

5.1. Sponsor

Date:	September 28, 2017
Applicant:	Skanray Technologies Private Limited, Plot # 15-17, Hebbal Industrial Area Mysore-570016, India
Contact Person:	Parul Chansoria, Regulatory Consultant, Elexes
Email Id:	parul@elexes.com
Phone:	650-528-2445

5.2. Establishment Registration Number

FDA establishment registration number:	3009001657

5.3. Device Name

Trade Name:	Skan C
Variants:	Skan C Mobile C-Arm X-Ray system-230V Variant (303-000187-1) Skan C Mobile C-Arm X-Ray system-110V Variant (303-000187-2)
Regulation Name:	Image-Intensified Fluoroscopic X-Ray System
Regulation Number:	892.1650
Product Code:	OXO -Primary & OWB-Secondary

5.4. Predicate Device

GE	OEC Fluorostar – K043076
Regulation Name:	Image-intensified fluoroscopic x-ray system
Regulation number:	892.1650
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO

5.5. Reference Device

Genoray	ZEN-2090 Pro - K091918
Regulation Name:	Image-intensified fluoroscopic x-ray system

Regulation number:	892.1650
Product Code:	OWB
Subsequent Product Codes:	JAA, OXO

5.6. Product Description

SKAN-C, is a mobile X-Ray C-Arm fluoroscopic device to assist in guiding medical intervention surgical procedures. The device can also be used for radiographic applications. The device is designed in such a way that it can be moved around and can be positioned for the required anatomical/clinical/procedural position.

SKAN-C, a Mobile Surgical C-Arm consists of two units, namely, Mobile Image Intensified C-Arm unit with generator, and a Work-Station for Image display, store and manipulation. C-Arm unit with generator is capable of movements which are essential for patient positioning, like horizontal travel, orbital movement, vertical movement, wig-wag movement and C rotation. The X-ray generator, X-Ray control system and collimator controls are housed in the C-Arm unit.

5.7. Indications for Use

The Skan-C, a Mobile Surgical C-Arm X-Ray System, is intended to provide Fluoroscopic and Radiographic images of the patient during diagnostic, surgical and interventional procedures.

Examples of clinical applications may include orthopaedic, GI procedures like endoscopy and cholenography, neurology, urology, vascular, critical care and emergency room procedures.

Skan-C is not recommended for cardiac applications.

Skan-C Surgical C-Arm is indicated for visualization in real time and/or recording of surgical region of interest and anatomy, using X-ray imaging technique.

5.8. Technology Characteristics

Major similarities between subject and predicate device.

		Skanray Skan-C	**GE OEC Fluorostar**	**SE Remark/Comment**
X-Ray Tube	Type	Stationary	Stationary	Same
	Focal Spot	0.6/1.8	0.5/1.5	Similar, slightly higher focal spot is to improve the thermal performance of the generator.
	Anode Heat capacity	45KHU	46KHU	Similar, Is the characteristic of X-Ray Tube. Meets the criteria of 10min continuous

		Skanray Skan-C	GE OEC Fluorostar	SE Remark/Comment
				exposure
Image Intensifier	Make	Thales	Thales/Thomson	
	Modes	Triple Mode, 9", 6" & 4.5"	Triple Mode, 9", 6" & 4.5"	Same
	DQE (%)	65	65	Same
Camera	Technology	CCD	CCD	Same
	Resolution	1k x 1k	1k x 1k	Same
Max Radiographic Power		2.2 kW	2.2 kW	Same
Loading Factors	Radiography KV Range	40-110 kV	36-110 kV	Better Stability within the range specified.
	mAs Range	200 mAs	52 mAs	Better mAs range for dense anatomy due to higher Focal Spot size.
	Fluoroscopy kV Range	40-110 kV	36-110 kV	Better Stability within the range specified
	Fluoroscopy mA Range (Normal and boost Mode)	0.2-8 mA	0.2-8 mA	Same
Physical Parameters	Free Space Available between Source and Detector	75 Cm	76 Cm	The minor difference in the physical parameters in terms of dimensions does not have any impact on the claimed indications for use.
	SID	95 Cm	98 Cm	
	C-Arm Depth	65 Cm	66 Cm	
	Horizontal Travel	20 Cm	20 Cm	
	Vertical Movement	40 Cm	43 Cm	
	Orbital Rotation	(125°)90°/-	(120°)90°/-	

		Skanray Skan-C	GE OEC Fluorostar	SE Remark/Comment
		35°	30°	
	Angulation	180° (+/-180°)	450° (+225°/-225°)	
	Wig-Wag	+-12,5°	+-10°	
Operating Environment	Input Energy Source	100-110 VAC, 50/60 Hz	100-110 VAC, 50/60 Hz	Same
	Operating Temperature Range	10deg C to 40deg C	10deg C to 40deg C	Same
	Operating Humidity Range	20- 80 % Non-Condensing	20- 80 % Non-Condensing	Same

Table 1: Technological characteristics

With the above comparison, the subject device, Skan C, is equivalent in technological and other characteristics to the predicate device, GE OEC Fluorostar.

5.9. FDA Guidance Documents

The following guidance documents were referred during development of the subject device:

1. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.
2. Off-The-Shelf Software Use in Medical Devices.
3. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
4. Draft Guidance for Industry and Food and Drug Administration Staff - Paediatric Information for X-ray Imaging Device Premarket Notifications
5. Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices - Guidance for Industry and Food and Drug Administration Staff.

5.10. Non-Clinical Tests:

The subject device has been evaluated and found to be compliant to safety and essential performance as per IEC 60601-1, accuracy of loading factors, reproducibility

of radiation output and imaging performance as per IEC 60601-2-54, recovery management, patient data, last image hold, image measuring functions as per IEC 60601-2-43, half value layer, leakage radiation in loading and normal state and stray radiation as per IEC 60601-1-3, conducted emission, radiated emission, harmonics, voltage fluctuations, electrostatic discharge (ESD), electrical fast transients (EFT), radiated RF electromagnetic field, continuous conducted RF, surges, power frequency magnetic field, voltage dips and short interruption as per IEC 60601-1-2, detective quantum Efficiency (DQE), spatial resolution, dynamic range, beam alignment, recovery time, dose requirements, stability of device characteristics with time, frame rate, reuse rate as per FDA guidance document for solid state X-ray imaging devices. The device also complies with FDA performance standards 21CFR 1020.30-1020.32. The verification and validation testing performed demonstrated compliance to the design requirements and intended use of SKAN C.

5.11. Clinical Tests:

Usability aspects of the device were tested by the users and independent participants including the setting up device and the post imaging processes. The results of the study did not reveal any discomfort or complex user interfaces for the intended purpose of the device.

Independent views of Radiologists were obtained on the imaging performances and the acquired images were of adequate quality for the indicated use. The results of the validation activities confirmed that the device is safe and effective for its intended application.

5.12. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the non-clinical tests, clinical tests and relative information provided in this premarket notification, we conclude that SKAN C Mobile C-arm X-ray system is substantially equivalent to predicate device with regard to safety and performance.