April 1, 2022

Skanray Technologies Limited
% Ankur Naik
Managing Director
IZiel Healthcare
14, Hadapsar Industrial Estate, Hadapsar
Pune, Maharashtra 411013
INDIA

Re: K220518
Trade/Device Name: SKANRAD 400
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR
Dated: February 18, 2022
Received: February 23, 2022

Dear Ankur Naik:

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,

Laurel Burk, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220518

Device Name
SKANRAD 400

Indications for Use *(Describe)*

The SKANRAD 400 is intended for use in generating X-Rays & radiographic images of human anatomy including skull, spinal column, chest, abdomen, extremities and other body parts in all general-purpose X-ray diagnostic procedures. The device is intended for use in paediatric and adult. It may be used in radiology departments, paediatrics, orthopaedics and clinics. Exposures may be taken with the patient sitting, standing, or lying in the prone or supine position. Device is designed to be used with conventional film/screen or computed radiography (CR) cassettes / DR system.
The system has been designed for indoor usage. It is intended for qualified medical personnel or operators who have been trained in the use of X-Ray equipment. SKANRAD 400 is not intended 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.

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K220518

510(k) Summary

510(k) summary of safety and effectiveness for SKANRAD 400 is provided in accordance with 21 CFR 807.92.

Date:	31 January 2022
Submitter (Owner):	Vasundhara R Regulatory Head Skanray Technologies Limited Plot# 15-17, Hebbal Industrial Area, Hebbal Mysore, Karnataka 570016, India P: +91 821 2415559 Email: vasundhara.r@skanray.com
510(k) Contact Person:	Ankur Naik Managing Director IZiel Healthcare 14, Hadapsar Industrial Estate, Hadapsar, Pune – 411013, India. P: +91 72762 2555 M: +91 7069553814 Email: ankur.naik@izielhealthcare.com
Device Trade Name:	SKANRAD 400
Regulation Number:	892.1680
Regulation Description:	A stationary x-ray system is a permanently installed diagnostic system intended to generate and control x-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment support, component parts, and accessories
Review Panel:	Radiology
Device Class:	Class II
Product Code:	KPR
Predicate Device:	RADspeed Fit (K173517) **Regulation number**: 21 CFR 892.1680 **Regulation name**: Stationary X-ray system **Device class**: II **Product code**: KPR, MQB **Review panel**: Radiology

Device description

SKANRAD 400 is a high frequency radiography system with 32kW generator X-Ray power. It can be used with table (recumbent position) as well as chest stand (standing position) for general radiography purpose. Electronic circuits incorporated for control, user interface, feedback circuits to ensure accuracy & reproducibility of X-Ray output. It consists of:

1. Tube head and collimator assembly
2. Floating table assembly
3. Chest stand assembly
4. HV generator assembly

SKANRAD 400 can be used with Film, Computed Radiography (CR) and Digital Radiography system image receptors along with associated image capture software. Skanray recommends using 510(k) cleared detectors and image acquisition systems to maintain compliance and quality: either wired or wireless with 14”x17” or 17” x 17” panels. Table 1 indicates the flat panel detectors and associated software, which are tested and verified with SKANRAD 400 to meet the required performance.

Table 1: Flat panel detectors and image acquisition software

Flat panel detector	Image Acquisition Software	Remarks
Varex PaxScan 4336W v4 (K161459)	DROC (Digital Radiography Operating Console) by E-COM Technology Ltd. (K130883)	DROC software compatible with all three detectors.
Varex PaxScan 4343RC (K172951)		

Intended Use / Indications for Use

The SKANRAD 400 is intended for use in generating X-Rays & radiographic images of human anatomy including skull, spinal column, chest, abdomen, extremities and other body parts in all general-purpose X-ray diagnostic procedures. The device is intended for use in paediatric and adult. It may be used in radiology departments, paediatrics, orthopaedics and clinics. Exposures may be taken with the patient sitting, standing, or lying in the prone or supine position. Device is designed to be used with conventional film/screen or computed radiography (CR) cassettes / DR system.

The system has been designed for indoor usage. It is intended for qualified medical personnel or operators who have been trained in the use of X-Ray equipment. SKANRAD 400 is not intended for mammography

Comparison to predicate devices

One predicate device is selected in this submission for the SKANRAD 400.

Predicate device: RADspeed fit (K173517)

The image quality of X-ray system depends on two main factors - the X-Ray generation and the Digital Radiography system. The X-Ray voltage generator, the

technology, design of the subject device is substantially equivalent to the predicate device, with minor changes in the ranges of kV, mA, and exposure time which does not affect the safety and effectiveness of the device. Image receptors that can be used with SKANRAD 400 include film, computed radiography and digital radiography. Flat panel detector and image acquisition software are not provided with the SKANRAD 400. To demonstrate that the subject device functions as intended it is tested with Varex PaxScan 4336Wv4 and Varex PaxScan 4343RC detectors along with the E-COM DROC image viewing software. The validation of the detector and software with SKANRAD 400 has been performed and validation activity has been documented. It does not affect the safety and efficacy of the device.

The details of the substantial equivalence between the subject device and predicate devices are explained as below:

Table 2: Comparison to Predicate Device

Comparable Properties	Subject Device	Predicate Device (K173517)	Comparison Results
Product name	SKANRAD 400	RADspeed fit	Not applicable
Manufacturer	Skanray Technologies Limited	Shimadzu Corporation	Not applicable
Regulation number	892.1680	892.1680	Identical
Product code	KPR	KPR, MQB	Identical
Product Class	II	II	Identical
Intended Use / Indications for Use	The SKANRAD 400 is intended for use in generating X-Rays & radiographic images of human anatomy including skull, spinal column, chest, abdomen, extremities and other body parts in all general-purpose X-ray diagnostic procedures. The device is intended for use in paediatric and adult. It may be used in radiology departments, paediatrics, orthopaedics and clinics. Exposures may be taken with the patient sitting, standing, or lying in the prone or supine position. Device is designed to be used with conventional film/screen or Computed Radiography (CR) cassettes/ DR system. The system has been designed for indoor usage. It is intended for qualified medical personnel	The RADspeed fit is intended to generate digital or conventional radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts of human anatomies in all routine radiography examinations. The RADspeed fit enables radiographic exposure of the whole body of all ages including paediatric patients. Exposures may be taken with the patient sitting, standing, or lying in the prone or supine position. The RADspeed fit uses portable or integrated flat panel detectors to generate diagnostic images by converting x-rays into electronic signals. The device is also designed to be used with conventional film/screen or computed radiography (CR) cassettes. The device is not intended for mammographic	Substantially equivalent

Comparable Properties	Subject Device	Predicate Device (K173517)	Comparison Results
	or Operators who have been trained in the use of X-Ray equipment. SKANRAD400 is not intended for mammography.	applications or tomographic techniques. The indications for use remain the same as those for the predicate, except for the removal of tomographic technique. WARNING: United States Federal Law restricts this device to sale by or on the order of a physician.	
Target Population	Adult, paediatric	Adult, paediatric	Identical
Performance Standard	1020.30 & 1020.31	1020.30 & 1020.31	Identical
Duration of Contact	<10 min	<10 min	Identical
Generator type	High Frequency	High frequency	Identical
Generator power level	32 kW	32kW/56kW	Identical
kV Range	40 kV–125 kV, 1 kV step	40-150 kV, 1 kV step	Substantial equivalent kV range of the subject device is within the range of the predicate device. The range covers all the general purpose diagnostic exposure required for the mentioned anatomies and it does not raise any concerns of safety and efficacy of the device.
mA Range	10-400 mA	10-500 mA (32 kW)	Substantial equivalent mA range of the subject device is within the range of the predicate device. This is considered as within the safety margin. mA is part of mAs (product of time and

Comparable Properties	Subject Device	Predicate Device (K173517)	Comparison Results
			current), and exposure values meets the required values for general diagnostic imaging procedure for all anatomical range, and it does not raise any concerns of safety and efficacy of the device.
Time range	5ms to 5 s	1 ms to 10 s	Substantial equivalent Time range of the subject device is within the range of the predicate device. All diagnostic imaging procedures are covered within this exposure duration, and it does not raise any concerns of safety and efficacy of the device.
X-ray tube focal spot	0.6 mm / 1.3 mm	0.6 mm / 1.3 mm	Identical
Type of Installation	Fixed (Tube- Floor Mount)	Fixed (Tube – Floor mount)	Identical
Aluminium Equivalence of Table and chest stand	< 1 mm Al	< 1 mm Al	Identical
Image acquisition	Digital	Digital	Identical
Image Receptor	Film/CR/DR	Film/CR/DR	Identical
Exposure method	Hand-switch/ Console	Hand-switch/ Console	Identical
User Interface	Touch console (Tube head & Operator)	Touch console (Tube head & Operator)	Identical
Device parts contact the patient	Patient table & chest bucky	Patient table & chest bucky	Identical
Power source	AC line	AC line	Identical

Comparable Properties	Subject Device	Predicate Device (K173517)	Comparison Results
Product Image			N/A
Electrical safety and EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-28 IEC 60601-2-54	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-3	Identical

Discussion of similarities and differences

SKANRAD 400 is intended for generating radiographic images of human anatomy for all general-purpose X-Ray diagnostic procedures in all patient population including pediatrics and adults and is not intended for mammographic application. Both predicate and subject device are indoor floor mounded X-ray system where X-Ray can be taken in all positions with the help of floor table and chest X-ray can be taken with the support of chest stand. The ranges for kV, mA and exposure duration are found to be within the predicate device range limiting to slightly on the lower side, which does not impact the intended application of the subject device as compared to predicate device. Image receptors of the subject device are film, CR, and DR which are same as predicate devices. User can choose their modality based on their requirements. The components of X-ray system like an X-ray generator and an X-ray tube are either identical or similar to predicate devices. The other components like the floor table, chest stand have no impact on the safety and effectiveness of the system. Materials of both floor table and chest stand are evaluated for biocompatibility. In addition, the subject device has been tested to the relevant performance standards as summarized below.

Performance data

The risks identified during risk analysis were reduced by applying suitable risk control measures and it was noted that there were no unacceptable risks after risk control measures.

Design verification and validation activities have been carried both in-house and by outsourcing to appropriate third-party vendors. The design verification, design validation and performance testing activities have been documented and indicate that the subject device is as safe and effective as the predicate device.

SKANRAD 400 complies with the following standards:

- IEC 60601-1 Edition 3.1 (2012)+EN 60601-1:2006+A1:2013+A12:2014 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-1-3:2008 (Second Edition) + A1:2013 Medical electrical equipment - Part 1: General requirements for safety -3. Collateral standard: General requirements for radiation protection in diagnostic X-Ray equipment.
- IEC 60601-2-54 Edition 1.2 2018-06 CONSOLIDATED VERSION Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.
- IEC 60601-2-28:2017 (Third Edition) Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-Ray tube assemblies for medical diagnosis.

- IEC 60601-1-6:2010/AMD1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62304:2006+A1:2015 Medical device software-Software Life-Cycle processes.
- ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process.
- ISO 14971:2007 Medical devices. Application of risk management to medical devices

Summary of clinical testing

As per FDA Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices document, subject device does not have major difference when compared to the predicate device. Considering this, non-clinical data is sufficient to support the safety and performance of SKANRAD 400. Hence clinical studies are not required.

Conclusion

All the above details collectively demonstrate that SKANRAD 400 is safe and effective when the device is used as labelled and is substantially equivalent to the predicate device.