March 4, 2022

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

Re: K212940
Trade/Device Name: SKANMOBILE, SKANMOBILE-DR
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB
Dated: January 12, 2022
Received: January 18, 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
Assistant Director
Diagnostic X-ray Systems Team
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)*
K212940

Device Name
SKANMOBILE and SKANMOBILE-DR

Indications for Use *(Describe)*
SKANMOBILE and SKANMOBILE-DR are intended for use in generating radio graphic images of human anatomy in all general-purpose x-ray diagnostic procedures for all patient population including paediatrics and adults. It may be used in radiology departments, emergency rooms, intensive care units, operating rooms, orthopaedics clinics, military camps, paediatric clinics, medical camps and small hospitals.
SKANMOBILE and SKANMOBILE-DR are indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities and other body parts with the patient sitting, standing or lying in the prone or supine position. The device has been designed for indoor usage and used/operated only by the trained & qualified physicians or x-ray technologist.
SKANMOBILE and SKANMOBILE-DR are not intended for mammographic applications.

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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Attachment 2-1: 005_510(k) Summary

510(k) Summary - K212940

510(k) summary of safety and effectiveness for SKANMOBILE and SKANMOBILE-DR is provided in accordance with 21 CFR 807.92.

Date:	12 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:	SKANMOBILE SKANMOBILE-DR
Regulation Number:	892.1720
Regulation Name:	Mobile X-Ray System
Regulation Description:	A mobile x-ray system is a transportable device system intended to be used to generate and control x-ray for diagnostic procedures. 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:	IZL MQB
Predicate Device(s):	• AMADEO M-DR mini, AMADEO M-AX mini (K182317) **Regulation number:** 892.1720 **Regulation name:** Mobile X-Ray system **Device class:** II **Product code:** IZL, MQB **Review Panel:** Radiology

	• DRAGON X SPSL4HC; DRAGON X SPSL8HC (K173299) **Regulation number:** 892.1720 **Regulation name:** Mobile X-Ray system **Device Class:** II **Product code:** IZL, MQB **Review Panel:** Radiology

Device description

The SKANMOBILE and SKANMOBILE-DR are X-ray systems which generates high frequency X-rays for diagnostic radiography in all patient population including pediatrics and adults.

Device variants

The following table lists the details of the variants of SKANMOBILE and SKANMOBILE-DR:

Table 1: List of Device Variants

Product Name	Part #
SKANMOBILE – HF diagnostic X-ray system, 230 VAC	303-000018-0
SKANMOBILE – HF diagnostic X-ray system, 110 VAC	303-000018-3
SKANMOBILE-DR – HF diagnostic X-Ray system, 230 VAC	303-000018-15
SKANMOBILE-DR – HF diagnostic X-Ray system, 110 VAC	303-000018-16

Device design

SKANMOBILE houses two microprocessors: one for control/supervisory functions and another for man-machine/user interface. The technology incorporates feedback circuits to ensure accuracy & reproducibility of X-Ray output.

SKANMOBILE consists of following sub-assemblies:

1. Tube head
2. SKANMOBILE trolley

SKANMOBILE-DR is a variant based on SKANMOBILE platform. SKANMOBILE-DR is a digital radiographic system designed for optimized image quality featuring wireless flat panel detector and operator console for digital imaging integrated with high frequency generator. SKANMOBILE-DR is similar to SKANMOBILE where tube head generator, collimator, and counter balancing mechanism remains same. The new or modified assemblies/sub-assemblies that are used in SKANMOBILE-DR are as follows:

1. Touchscreen operator console.
2. Modified brake mechanism for wheels
3. Modified cassette tray to house the cassette / flat panel detectors.

Both SKANMOBILE and SKANMOBILE-DR consists of software/firmware which enables the operation of the devices. The design and development of the software has been executed as per the requirements of ISO 62304. User interface is provided via UART interface from Console System. Software Control System of Control Firmware is of Master – Slave in nature. The programming language adopted is ANSI C and the software architecture follows a simple Call and Return flow of statements and modules.

Flat panel detectors and image acquisition software integration details

Table 2 explains the compatibility between available options of flat panel detectors and image acquisition software used in the X-ray systems.

Table 2: Flat panel detectors and image acquisition software integration

Flat Panel Detector	Image Acquisition Software	Remarks
CE certified / FDA cleared Compatible Flat Panel Detector Varex Paxscan 4336Wv4 can be used with the X-Ray system	FDA cleared Image Acquisition System with compatible Flat Panel Detector can be used.	SKANMOBILE-DR is verified and validated with Varex Flat Panel Detector Paxscan 4336Wv4 and ECOM Image Acquisition Software with customized OEM title
CE certified / FDA cleared Compatible Flat Panel Detector CareView 1500P can be used with the X-ray system	FDA cleared Image Acquisition System with compatible Flat Panel Detector can be used.	SKANMOBILE-DR is verified and validated with CareView 1500P detector and ECOM Image Acquisition Software with customized OEM title

The above-mentioned specific combinations of flat panel detectors and image acquisition software are compatible with all types/configurations of other components (x-ray generator, x-ray tube, collimator, and mechanicals).

The device is packaged inside a corrugated box with, appropriate labels and the user manual after cleaning the entire unit. The device is secured to the wooden pallet and covered for adequate safety.

The device is packed appropriately as required by the mode of transportation.

Intended Use / Indications for Use

SKANMOBILE and SKANMOBILE-DR are intended for use in generating radio graphic images of human anatomy in all general-purpose x-ray diagnostic procedures for all patient population including paediatrics and adults. It may be used in radiology

departments, emergency rooms, intensive care units, operating rooms, orthopaedics clinics, military camps, paediatric clinics, medical camps and small hospitals.

SKANMOBILE and SKANMOBILE-DR are indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities and other body parts with the patient sitting, standing or lying in the prone or supine position. The device has been designed for indoor usage and used/operated only by the trained & qualified physicians or x-ray technologist.

SKANMOBILE and SKANMOBILE-DR are not intended for mammographic applications.

Comparison to predicate devices

Two predicate devices are selected in this submission for the SKANMOBILE and SKANMOBILE-DR.

Predicate device 1: AMADEO M-DR mini, AMADEO M-AX mini (K182317)

Predicate device 2: DRAGON X SPSL4HC; DRAGON X SPSL8HC (K173299)

The details of the substantial equivalence between the subject device and predicate devices are explained in Table 3:

Table 3: Comparison to Predicate Devices

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Product name	SKANMOBILE and SKANMOBILE-DR	AMADEO M-DR mini, AMADEO M-AX mini	DRAGON X SPSL4HC; DRAGON X SPSL8HC	Not applicable
Manufacturer	Skanray Technologies Limited	Oehm Und Rehbein Gmbh	Sedecal SA	Not applicable
Regulation number	892.1720	892.1720	892.1720	Identical
Product code	IZL, MQB	IZL, MQB	IZL, MQB	Identical
Product Class	II	II	II	Identical

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Intended Use / Indications for Use	SKANMOBILE and SKANMOBILE-DR are intended for use in generating radio graphic images of human anatomy in all general-purpose x-ray diagnostic procedures for all patient population including paediatrics and adults. It may be used in radiology departments, emergency rooms, intensive care units, operating rooms, orthopaedics clinics, military camps, paediatric clinics, medical camps and small hospitals. SKANMOBILE and SKANMOBILE-DR are indicated for taking radiographic exposures of the skull, spinal column, chest, abdomen, extremities and other body parts with the patient sitting, standing or lying in the prone or supine position. The device has been designed for indoor usage and used/operated only by the trained & qualified physicians or x-ray technologist. SKANMOBILE and SKANMOBILE-DR are not intended for mammographic applications.	These Portable Diagnostic Radiographic Systems are 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. (Not for mammography).	These Portable Diagnostic Radiographic Systems are 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. (Not for mammography).	Substantially Equivalent

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Line power requirements	230 VAC / 110 VAC	100-240 VAC	100-240 VAC / 220 – 240 VAC	Substantially Equivalent Mains power voltage range are country specific. Devices are designed to accept either 230VAC/220VAC or 100VAC/110VAC, depending on where they are placed. The mains input labelling will be declared to indicate the device compliance to the mains input meeting specified country mains regulation and hence does not raise the level of safety concern and affect performance.
Generator type	High Frequency	High frequency	High frequency	Identical

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Generator power level	4 KW	5KW	4KW, 8KW	Substantially equivalent Maximum generator power is the maximum power derived from the maximum kV and mA drawn. The device generates kV and mA optimal for the different anatomy as defined by the accepted anatomically programmed radiography (APR) table, which are independent of power drawn by the system. Thus, minor difference in the power does not change the intended application. Additionally, electrical safety and EMC testing has been performed on the subject devices and it has been observed that the device performs as intended and hence does not raise the level of safety concern and affect performance.

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Peak voltage	100 kV	110 kV	125 kV	Substantially equivalent Minor difference in the peak voltage applied across the x-ray tube indicates differences in the device construction and the object distance from the source. However, these changes do not change the intended device application. The quality of the images obtained from the subject devices were analysed by a radiographer and a radiologist and it was found the images were of good quality which were easily read by the radiologist and hence does not raise the level of safety concern and affect performance.

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
High voltage range	40 kV–100 kV, 1 kV step	40-100 kV, 1 kV step	40-125 kV, 1 kV step	Substantially equivalent X-ray tube voltage setting range is 40kV to maximum peak X-ray voltage, which the tube can handle. Range is a minor element, which can be different but it still maintains the same intended application and hence does not raise the level of safety concern and affect performance.
mAs range	0.1 mAs to 250 mAs	0.4 -100 mAs	0.1 mAs to 250 mAs	Substantially equivalent Product of X-ray tube current and time is termed as mAs, which is a dependent parameter of power rating and voltage rating which as mentioned above does not change the intended application. APR table recommends the user to use referred value or user can set a value which is appropriate for that examination. It does not raise the level of safety concern and affect performance.

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Collimator	Manually operated, LED light source, Maximum light field of 48 X 48 cm at 1 m SID, 30 Sec timer.	POSKOM PCMAX-100CAH: LED lamp, Maximum light field of 47 X 47 cm @ 100 cm SID, 30 Sec timer.	Ralco R72S: Manual, white LED, Single layer square field of 43 X 43 cm at 100 cm SID, 125 kVp. (K030487)	Substantially equivalent Collimator is the device which restricts the X-ray beam within the specified useful area avoiding unintended radiation on the body. Different light field indicates the area of detector that can be used with the system and does not change the intended application. LED or white LED or lamp are the light sources which are used to visualize the area of primary beam on selected object. The principle of operation and usage remain same. It does not raise the level of safety concern and affect performance.

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Image Receptor	DR	DR	DR	Substantially Equivalent SKANMOBILE variant supports image reception through film /computed radiography (CR)/digital radiography (DR) technologies and user can use any of these image reception technologies which can integrate with SKANMOBILE with the software inbuilt in the image receptors. SKANMOBILE-DR variant supports DR with its own customized Skanview software.
Digital Panel Models and their Clearance Numbers	Nexus DR™ Digital X-ray Imaging System with PaxScan 4336Wv4 (K161459) CareView 1500P X-ray Flat Panel Detectors (K162178)	PerkinElmer XRpad2 4336 detector (K161966) or the XenOR 35CW (CareRay CareView1500CW) (K150929)	Toshiba FDX3543RP or FDX3543RPW (K130883)	Substantially Equivalent The subject device utilizes a different X-ray flat panel detector; however, the flat panel detectors used by the subject device are already previously cleared by the FDA and the testing demonstrates that it does not raise the level of safety concern and affect performance.

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Digital Panel Specifications	PaxScan® 4336Wv4: Pixel pitch: 139 µm Detector Element Matrix: 3072 x 2560 CareView 1500P: Pixel pitch 154 µm Image Matrix Size: 2304 × 2816 pixels	XRpad2 4336: 100 µ, 3524 × 4288 pixels XenOR 35CW (CareView1500CW): 154 µ 2304 x 2816 pixels	FDX3543RP: 143 µm pixel pitch, 2448 ×2984 pixels FDX3543RPW: 140 µ, 2466 ×3040 pixels	Substantially Equivalent The resolution of the number of horizontal and vertical sensing element on the detector and difference in the size does not change the intended application. This parameter is defined under the limited spatial resolution or detectable size of anatomy. Spatial resolution for general radiography is generalized at 1.6 lp/mm. This does not raise the level of safety concern and affect performance.
Detector Technology	Direct Deposition CsI	Direct Deposition CsI	Direct Deposition CsI	Identical
Detective Quantum Efficiency (DQE) of Digital Panel	**Paxscan 4336Wv4:** 0.242 @ 1cycle/mm 0.125 @ 2cycles/mm 0.04 @ 3cycles/mm **CareView1500P (@RQA5, 30µGy):** ~ 65% @ (0 lp/mm) ~ 20% @ (3 lp/mm)	**XRpad2 4336:** 75% (0 cy/mm) 60% (1 cy/mm) 40% (3 cy/mm) **CareView1500CW:** ~ 65% @ (0 lp/mm) ~ 20% @ (3 lp/mm)	FDX3543RP: >70% FDX3543RPW: >70% @ 0 lp/mm	Substantially Equivalent The performance of the flat panel detectors with respect to the claimed DQE was evaluated and it was demonstrated that the DQE values measured were comparable to the values claimed by the detector manufacturer. This does not raise the level of safety concern and affect performance.

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Modulation Transfer Function (MTF) of Digital Panel	**Paxscan 4336Wv4:** 0.521 @ 1cycle/mm 0.206 @ 2cycles/mm 0.08 @ 3cycles/mm **CareView1500P:** ~ 70 % @ (1 lp/mm) ~ 40% (@ 2 lp/mm) ~ 22% (@ 3 lp/mm)	**XRpad2 4336:** 70% (1 cy/mm) 40% (2 cy/mm) 15% (4 cy/mm) **CareView1500CW:** ~ 70 % @ (1 lp/mm) ~ 40% (@ 2 lp/mm) ~ 22% (@ 3 lp/mm)	FDX3543RP: 36% typ. (2.0 lp/mm, 70kVp, 1x1) FDX3543RPW: Unknown	Substantially Equivalent The performance of the flat panel detectors with respect to the claimed MTF was evaluated and it was demonstrated that the MTF values measured were comparable to the values claimed by the detector manufacturer. This does not raise the level of safety concern and affect performance.
Communication interface	Wireless Data Interface: Dual Band (2.4GHz and/or 5GHz) 802.11a/b/g/n/ac	Gb Ethernet or 802.11n WiFi	Unknown	Identical
Focal spot	1.8 mm	1.8 mm	0.5 – 1.8 mm, 0.6 – 2.8 mm	Identical

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Software	Customized E-COM Software called SkanView, a digital radiography operational software	DICOMPACS DX-R	ECOM software as cleared in K130883	Substantially Equivalent SKANMOBILE and SKANMOBILE-DR utilizes customized E-COM software. The E-COM software is 510(k) cleared in K193644. The customization of the 510(k) cleared software has been validated and documented as part of software validation & verification. It has been demonstrated that the customization of the E-COM software does not raise the any new questions of safety or performance.

Comparable Properties	Subject Device	Predicate Device 1 (K182317)	Predicate Device 2 (K173299)	Comparison Results
Connection	Wi-Fi	Ethernet or Wi-Fi	Ethernet or Wi-Fi	Substantially Equivalent Ethernet and Wi-fi are the connectivity modules with external devices for the transmission of data. Ethernet needs cable connectivity for data transfer whereas Wi-fi is wireless data transfer (no cable is required). Both have the same functionality of data transmission. This does not raise the level of safety concern and affect performance.
DICOM	Yes	Yes	Yes	Identical
Power source	AC line	AC line	AC line	Identical
Performance Standard	21 CFR 1020.30 and 1020.31	21 CFR 1020.30	21 CFR 1020.30	Substantially Equivalent In addition to 21 CFR 1020.30, subject device also shows compliance to 21 CFR 1020.31 and the test report is available in Section 18 (Att-18-9).
Electrical safety and EMC	IEC-60601 IEC-60601-1-2 IEC 60601-1-3 IEC 60601-1-28 IEC 60601-2-54	IEC-60601 IEC-60601-1-2 IEC 60601-1-3 IEC 60601-2-54	IEC-60601 IEC-60601-1-2 IEC 60601-1-3 IEC 60601-2-54	Identical

Discussion of similarities and differences

SKANMOBILE and SKANMOBILE-DR 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. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. The device shall be used or operated only by the trained & qualified physicians or X-ray technologists. This device is not intended for Mammography application. This device utilizes FDA cleared X-ray flat panel detectors and image processing software which are the associated components of any digital X-Ray diagnostic system. The other components of the imaging system such as the X-Ray generator and X-Ray tube are either identical or similar to the predicate devices. The remaining other components have no impact on the safety and performance of the system. In addition, the subject device confirms to the following performance standards as summarized below.

Performance data

SKANMOBILE and SKANMOBILE-DR are developed by implementing various design control activities including design verification, design validation and risk analysis.

The risks identified during risk analysis were reduced by applying suitable risk control measures and it was noted that there were no unacceptable risks remained after applying risk control measures. Though the X-Ray is harmful to the patient or user during intended use, the clinical benefit in terms of image guiding for diagnosis and treatment outweighs the risk caused by X-ray. The device is intended to be used in hospitals and clinics by trained operators.

Design verification and validation activities have been carried both in-house and by outsourcing to appropriate third-party vendors. A summary of the design verification, design validation and performance testing activities is elaborated in section 18 of this submission.

The SKANMOBILE and SKANMOBILE-DR comply with following standards:

- IEC 60601-1:2005+AMD1:2012 (Edition 3.1) 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 Collateral standard: Electromagnetic compatibility requirements and tests
- IEC 60601-1-3:2008 (Edition 2) General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-54:2018 Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 60601-2-28:2010 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 62366:2007/AMD 1:2014 Medical devices — Application of usability engineering to medical devices
- IEC 62304:2006 Medical device software — Software life cycle processes
- ISO 14971:2012 Medical devices. Application of risk management to medical devices.
- IEC 62494-1 Edition 1.0 (2008-08) Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography.
- IEC 62220-1-1 Edition 1.0 2015-03 Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging.
- NEMA PS 3.1 - 3.20 (2016) Digital Imaging and Communications in Medicine (DICOM) Set.
- IEC 61910-1 Edition 1.0 2014-09 Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy.
- IEC 60336 Fourth edition 2005-04 Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots [Including: Technical Corrigendum 1 (2006)]
- IEC 60522:1999: B: 2003 Medical electrical equipment - Diagnostics X-rays - Part 1: Determination of quality equivalent filtration and permanent filtration.
- ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices.
- ISO 15223-1 Third Edition 2016-11-01 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.
- ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems.

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 modifications when compared to predicate devices. Additionally, the flat panel detector used in the subject device has been previously cleared by US FDA. Considering this, non-clinical data is sufficient to support the safety and performance of SKANMOBILE and SKANMOBILE DR. Hence clinical studies are not required.

Conclusion

Technological differences from the predicate devices include different detectors. Although some of the components differ from the predicate devices, the subject device utilizes previously cleared X-ray flat panel detectors and image processing software. The other components of the imaging system such as the X-ray generator and X-ray tube are either identical or similar to the predicate devices. Despite the few differences, after analysis of all test information, including the indications for use and test data it is collectively demonstrated that the SKANMOBILE and SKANMOBILE-DR are as safe and effective as the predicate devices when used as labelled and are substantially equivalent to predicate devices.