December 16, 2025

Skanray Technologies Limited
% Vasundhara R
Head - Regulatory
Plot# 15-17, Hebbal Industrial Area
MYSORE, KARNATAKA 570016
INDIA

Re: K251893
Trade/Device Name: Skan C Pulsar
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB OXO JAA
Dated: June 12, 2025
Received: November 18, 2025

Dear Vasundhara R:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251893

Device Name
SKAN C Pulsar

Indications for Use *(Describe)*
The SKAN C Pulsar, a Mobile Surgical C-Arm X-Ray System, is intended to provide Fluoroscopic images of patients during Diagnostic, Surgical and Interventional procedures. SKAN C Pulsar is to be used by adequately trained, qualified and authorized healthcare professionals. Clinical Applications may include Orthopedic, GI Procedure, Neurology, Urology Procedures, Vascular in Critical Care and Emergency Room Procedures.
SKAN C Pulsar is not recommended for Cardiac Applications.
SKAN C Pulsar 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.

510(k) summary: Skan C Pulsar

510(k) number: K251893

In accordance with 21 CFR 807.92, following information is provided:

Date	18 Nov 2025
510(k) owner	Skanray Technologies Limited Plot #15-17, Hebbal Industrial Area, Mysore, Karnataka – 570016, INDIA
Submitter	Vasundhara R Head – Regulatory Affairs Skanray Technologies Limited Contact number: +91 821 2415559 Email: vasundhara.r@skanray.com
Trade name	SKAN C PULSAR
Device class	II
Device common name	Interventional Fluoroscopic X-Ray System
Regulation name	Image-intensified Fluoroscopic x-ray System
Regulation number	21 CFR 892.1650
Product code	OWB

Subsequent product code	OXO, JAA
Primary Predicate device	Extron 5, Extron 7 510(k) Clearance: K230871 Device class: II Device common name: Interventional Fluoroscopic X-Ray System Regulation description: Image Intensified Fluoroscopic X-Ray System Regulation number: 21 CFR 892.1650 Manufacturer: DRTECH Corporation
Secondary Predicate device	Skan C Mobile C-arm X-Ray System – 230V Variant (3030-000187-1), Skan C Mobile X-Ray system – 110V Variant (3030-00187-2) 510(k) Clearance: K170946 Device class: II Device common name: Image Intensified Fluoroscopic X-Ray System Regulation description: Image Intensified Fluoroscopic X-Ray System Regulation number: 21 CFR 892.1650 Manufacturer: Skanray Technologies Limited
Reference device 1	Digiscan FDX 510(k) Clearance: K200218 Device class: 2

	Device common name: Interventional Fluoroscopic X-Ray System Regulation description: Image Intensified Fluoroscopic X-Ray System Regulation number: 21 CFR 892.1650 Manufacturer: Allengers Medical Systems Limited
Reference device 2	Cios Alpha 510(k) Clearance: K181560 Device class: II Device common name: Interventional Fluoroscopic X-Ray System Regulation description: Image Intensified Fluoroscopic X-Ray System Regulation number: 21 CFR 892.1650 Manufacturer: Siemens Medical Systems USA, Inc.
Device description	The SKAN C Pulsar, a Mobile C-Arm X-Ray System, is intended to provide Fluoroscopic images of patients during Diagnostic, Surgical and Interventional procedures. SKAN C Pulsar is to be used by adequately trained, qualified and authorized healthcare professionals. Clinical Applications may include Orthopedic, GI Procedure, Neurology, Urology Procedures, Vascular in Critical Care and Emergency Room Procedures. SKAN C Pulsar is a Mobile fluoroscopy C-Arm consisting of two main units: a) C-arm main unit b) A Workstation or Monitor Cart The C-arm unit is composed of an X-ray tube, a flat panel detector, a collimator, a generator, a touch panel, foot switch, hand switch and a Console. C-arm has provision for mechanical movement of C-arm for Orbital and Yoke Rotation along with vertical and wig-wag movements.

	Workstation or Monitor cart is composed of a monitor, keyboard and computing system. The operating principle of the device is to expose X-ray, which are passed through the human body and falls on the sensor. The intensity of X-ray can be adjusted to required level. Detector follows two step conversion. It converts X-ray into light and Light is converted into electrical signal. Electrical signal is than digitized and stored. This stored information is processed and displayed on the monitor. The displayed images can be saved or transmitted to an external storage device.
Intended use / Indication for use	The SKAN C Pulsar, a Mobile Surgical C-Arm X-Ray System, is intended to provide Fluoroscopic images of patients during Diagnostic, Surgical and Interventional procedures. SKAN C Pulsar is to be used by adequately trained, qualified and authorized healthcare professionals. Clinical Applications may include Orthopedic, GI Procedure, Neurology, Urology Procedures, Vascular in Critical Care and Emergency Room Procedures. SKAN C Pulsar is not recommended for Cardiac Applications. SKAN C Pulsar 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.

Primary and Secondary Comparable Properties Table

Predicate Device Manufacturer and Model	**510(k) Number**	**Comparable Properties**
Primary Predicate DRTECH Corporation: Extron 5, Extron 7	K230871	Indication for use System Image Acquisition and X-ray generation Image Acquisition and Transmission Detector Technology
Secondary Predicate Skanray: Skan C	K170946	Indication for use Constructional features

Reference Device Manufacturer and Model	510(k) Number	Comparable Properties
Allengers Medical Systems Limited: Digiscan FDX	K200218	Detector Technology
Simens Medical Systems USA: Cios Alpha	K181560	Detector Technology

Selection Criteria for the Predicate Device

Valid Predicate Device	Well Established method	Meets or exceeds expected predicate performance	Unmitigated use-related or design related safety issues	Associated design related recall
K-183040	Used relevant methods that were published in the public domain	Meets the performance	No known unmitigated use related of design related safety issues	Few Class II recalls made and were effectively addressed
K-200218	Used relevant methods that were published in the public domain	Meets the performance	No known unmitigated use related of design related safety issues	No design related recall identified
K-230871	Used relevant methods that were published in the public domain	Meets the Performance	No known unmitigated use related of design related safety issues	No design related recall identified
K181560	Used relevant methods that were published in the public domain	Meets the Performance	No known unmitigated use related of design related safety issues	No design related recall identified
K170946	Used relevant methods that were published in the public domain and with Skanray internal data	Meets the Performance	No known unmitigated use related of design related safety issues	No design related recall identified

Discussion:

Primary Predicate Device 510k cleared (K230871), is considered as it is legally marketed device which is found to be consistent with IFU statements and device labeling. It has the same intended use when compared to subject device. Technological characteristics are similar.

Secondary Predicate Device K170946 from Skanray Technologies Ltd, considered as Secondary Substantial device, which has similar construction features when compared to subject device with the same intended use.

Skan C Pulsar incorporates a Flat Panel Technology, for which two more 510k cleared reference devices K200218 and K181560, are used to evaluate the safety and performance of the Detectors with similar technologies

Technological characteristics of the subject device in comparison to those of the predicate device:

Parameter	Subject Device	Primary Predicate	Secondary Predicate	Remark
Manufacturer	Skanray Technologies Limited	DRTECH Corporation	Skanray Technologies Limited	--
510(k) Code	K251893	K230871	K170946	--
Model	Skan C Pulsar	Extron 5 and Extron 7	Skan C	--
Regulatiory Description	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Same
Device Name	Interventional fluoroscopic x-ray system	Interventional fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system, mobile	Subject and primary predicate device are same.
Regulatory Class	Class II	Class II	Class II	Same

Product Code	OWB, OXO, JAA	OWB, OXO, JAA	OXO, OWB	Subject and primary predicate devices are same.
Intended use	The Skan C Pulsar, a Mobile Surgical C-arm X-ray system, is intended to provide Fluoroscopic images of patient during Diagnostic, Surgical and Interventional procedures. SKAN C Pulsar is to be used by adequately trained, qualified and authorized healthcare professionals. Clinical Applications may include Orthopedic, GI Procedure, Neurology, Urology Procedures, Vascular in Critical Care and Emergency Room Procedures. SKAN C Pulsar is not recommended for Cardiac Applications. SKAN C Pulsar is indicated for visualization in real time and/or recording of surgical region of interest and anatomy, using X-ray imaging technique.	EXTRON5 and EXTRON 7 are a mobile fluoroscopic X-ray system with high output capacity, high thermal capacity and high-resolution image processing system, which provides X-ray images of the patient's anatomy during surgery or treatment. This device plays an important role in emergency injury treatment, orthopedic surgery, neurosurgery surgery, bone surgery, etc. This device has a function to save important a specific image as records, so you can easily search for the images and transmit it to the PACS system in the hospital to help the medical staff in diagnosis. Examples of a clinical application may include: Neurosurgery, Orthopedics, Anesthesiology, Urology, Gynecology, Internal	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.	Similar

		Medicine (※ This device is not intended for mammography applications.)		
Target Population	Patients who need X-Ray fluoroscopy images including Adults and pediatrics	Patients who need X-Ray fluoroscopy images including Adults and pediatrics	Patients who need X-Ray fluoroscopy images including Adults and pediatrics	Same
System and Sub-system Design	Device Major Subsystems are: X-Ray Generator with mono-block design Flat Panel Detector C-Arm Mechanical system C-Arm Orbital and Rotation, Horizontal travel, Wig-Wag movement and Vertical C-movement. User Console at C side for operator to use User Console at Workstation to display the captured x-ray image on the screen Both C-Arm and Workstation are mobile	Device Major Subsystems are: X-Ray Generator with mono-block design Flat Panel Detector C-Arm Mechanical system C-Arm Orbital and Rotation, Horizontal travel, Wig-Wag movement and Vertical C-movement. User Console at C side for operator to use User Console at Workstation to display the captured x-ray image on the screen Both C-Arm and Workstation are mobile	Device Major Subsystems are: X-Ray Generator with mono-block design Flat Panel Detector C-Arm Mechanical system C-Arm Orbital and Rotation, Horizontal travel, Wig-Wag movement and Vertical C-movement. User Console at C side for operator to use User Console at Workstation to display the captured x-ray image on the screen Both C-Arm and Workstation are mobile	Same
Power Output	Max 6kW	Extron 5: Max 4.8kW Extron 7: Max 15kW	Max 2.2kW / 3.5kW	Similar: The specifications have been enhanced to enable operation at

				power levels up to 6kW, which is comparable to EXTRON 5 (primary predicate device) and Skan C (secondary predicate device). This does not give rise to any novel concerns regarding safety and effectiveness.
X-Ray Tube	Rotating Anode	Rotating Anode	Stationary Anode	Same: Both Subject device and Primary Predicate device make use of Rotating Anode X-Ray tube technology. Similar: Secondary Predicate device is lower powered x-ray system making use of stationary anode x-ray tube.
Fluoroscopic Mode Parameters range	1. kV Range: 40 – 120kV 2. mA Range: Max 60 mA	1. kV Range: 40 – 120kV 2. mA Range: Max 60mA (EXTRON 7) and Max 40mA (Extron 5)	1. kV Range: 40 – 110kV 2. mA Range: Max 12 mA	Similar: Primary Predicate device and subject device have the same range of kV and mA. Secondary Predicate device parameters are limited to 110kV and 12mA due to X-Ray tube type and low powered device.

				This does not give rise to any novel concerns regarding safety and effectiveness.
Radiographic Mode Parameters range	Not Applicable	EXTRON 5: Not Applicable EXTRON 7: kV Range : 40 to 120kV mA Range : Up to 150mA	1. kV Range: 40-110kV 2. mAs Range: Max 200 mAs	Similar: Radiographic Mode is not provided in both Primary Predicate EXTRON 5 and Subject device with comparable power outputs. Secondary predicate device has lower power Radiographic output. Since the intended function is to provide Fluoroscopy x-ray system, Radiographic mode is deemed as a feature. This does not give rise to any novel safety concerns, as in both cases, single image is displayed and recorded.
Dimension	Immersion Depth: 74 cm	Immersion Depth: 74 cm	Immersion Depth: 65 cm	Similar: Immersion depth is the distance from the beam center to the C section surface used to reach the far side of the human body.

				This is same as Primary Predicate device. Better when compared to the secondary predicate device. Alteration in the dimension does not give rise to any novel concerns regarding safety and effectiveness.
Dimension	Free Space: 82.5 cm	Free Space: 80 cm	Free Space 75 cm	Similar: Free Space is the space available between Source and the detector to accommodate Human body for the purpose of fluoroscopy exposure during the procedure. This is same when compared to Primary Predicate Device. Slightly better than when compared to Secondary Predicate Device. Minor alteration in the dimension does not give rise to any novel concerns regarding safety and effectiveness.
Dimension	Orbital Movement: Total: 147º	Orbital Movement: Toral: 165º	Orbital Movement: Total: 125º	Similar:

				Orbital Rotation is the rotation around the patient in a plane perpendicular to c-arm moving in an arc like path. This facilitates capturing images from different arc angles for convenience of positioning. Minor changes in Orbital movement does not give rise to any novel concerns regarding safety and effectiveness.
Exposure Switch	Wired Foot switch and Hand Switch	Wired and Wireless Foot switch and wired Hand Switch	Wired Foot switch and Hand Switch	Similar except for wireless option. Predicate devices and subject devices have same wired Foot Switch and Hand Switch. Wireless Hand Switch and Hand Switch are additional features for convenience doing the same intended function of wired one. This does not give rise to any novel concern over the Safety and Performance of the device.
Laser Guide	Yes	Yes	Yes	Same

Collimator	Available, Rectangular Collimation	Available, Rectangular Collimation	Available, Rectangular with Circular Collimation	Same
Deployment Method	Used for visualizing internal organ of the body. Used inside the procedure room with controlled environment	Used for visualizing internal organ of the body. Used inside the procedure room with controlled environment	Used for visualizing internal organ of the body. Used inside the procedure room with controlled environment	Same
Operating Principle	The operating principle of the device is designed to expose the patient to X-ray beams. The range of X-ray irradiation are adjusted by the collimator. X-rays can penetrate into the human and hits the detector surface. X-ray photons are converted into light. The light is then converted into electrical signals through the sensor. The electrical charges are transmitted as the sensor output and converted into signals. These signals are digitized and captured by memory. The captured images are processed and displayed on the monitor.	The operating principle of the device is designed to expose the patient to X-ray beams. The range of X-ray irradiation are adjusted by the collimator. X-rays can penetrate into the human body through a two-step conversion process. X-ray photons are converted into light. The light is then converted into electrical signals through the sensor. The electrical charges are transmitted as the sensor output and converted into signals. These signals are digitized and captured by memory. The captured images are processed and displayed on the monitor.	The operating principle of the device is designed to expose the patient to X-ray beams. The range of X-ray irradiation are adjusted by the collimator. X-rays can penetrate into the human body and hits the detector surface. X-ray photons are converted into light. The light is then converted into electrical signals through the sensor. The electrical charges are transmitted as the sensor output and converted into signals. These signals are digitized and captured by memory. The captured images are processed and displayed on the monitor.	Same

Detector Technology	Flat Panel Detector	Flat Panel Detector	Not Applicable	Same
Detector Details	9” Panels: CMOS panel: Pixel matrix: 1416 x 1416 ASi panel: Pixel matrix 1024 x 1024 **IGZO Panel: Pixel matrix 1536 x 1536** 12” Panels: CMOS panel: Pixel matrix 1943 x 1943 ASi panel: Pixel matrix 1536 x 1536 **IGZO Panel: Pixel matrix 2048 x 2048**	9” Panel Size: 210 x 210 mm IGZO Panel: EXPD 2121P Pixel Matrix 1500 x 1500 DQE 70% @ 0.5lp/mm MTF 60% @ 1lp/mm Pixel Pitch : 140um Gray Scale: 16 bit 12” Panel IGZO Panel: EXPD 3030P Pixel matrix 2048 x 2048	Not Applicable	IGZO Detector: Similar Technology. Slight difference in pixel size and size do not impact safety and performance. CMOS and Amorphous Silicon (AsI) technology and specification are compared with reference devices mentioned in subsequent table.

Submission of 510(k) for Solid State X-Ray Imaging Devices includes the evaluation for detectors specified as per the following performance specifications, identified in the SSXI guidance, showing comparable performance of Skan C Pulsar to its reference devise. Following table indicates comparative information.

Details of Comparable specifications with cleared detector's specifications.

	Subject Device	**Reference Device 1: K200218**	**Reference Device 2: K181560**	**Remarks**
Device Classification Name	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Image-intensified fluoroscopic x-ray system	Same
Primary Product Code	OWB	OWB	OWB	Same
Classification	II	II	II	Same
Detector Sizes / Variants	20 cm x 20 cm (8inch) aSi (amorphous silicon TFT technology) Size: 20.5 cm x 20.5 cm Detector matrix: 1,024 x 1,024 pixels DQE> 75% MTF>50%@1lp/mm Pixel size 200µm Gray scale 16bit	20 cm x 20 cm (8inch) aSi (amorphous silicon TFT technology) Size: 20.5 cm x 20.5 cm Detector matrix: 1,024 x 1,024 pixels DQE: 78% MTF>50%@1lp/mm Pixel size 200µm Gray scale 16bit	--	Similar: Slight differences in DQE do not have influence on safety and effectiveness of C-arm.
	20 cm x 20 cm (8inch) (CMOS TFT technology) Size: 21.5 cm x 21.5 cm Detector matrix: 1,416 1,416ixels DQE: 70%	--	20 cm x 20 cm (8inch) (CMOS TFT technology) Size: 21.5 cm x 21.5 cm Detector matrix: 1,416 1,416ixels DQE: 70%	Same

	MTF>50%@1lp/mm Pixel size 151.8 um Gray scale 14bit		MTF>50%@1lp/mm Pixel size 151.8 um Gray scale 14bit	

	Subject Device	**Reference Device 1: K200218**	**Reference Device 2: K181560**	**Remarks**
Detector Sizes / Variants	30 cm x 30 cm (12inch) aSi (amorphous silicon TFT technology) Size: 30 cm x 30 cm Detector matrix: 1536 x 1536 pixels DQE > 70% MTF > 50%@1lp/mm Pixel size 200µm Gray scale 16bit	30 cm x 30 cm (12inch) aSi (amorphous silicon TFT technology) Size: 30 cm x 30 cm Detector matrix: 1536 x 1536 pixels DQE > 70% MTF > 50%@1lp/mm Pixel size 200µm Gray scale 16bit	--	Similar: Slight differences in DQE do not have influence on safety and effectiveness of C-arm.
	30 cm x 30 cm (12inch) (CMOS TFT technology) Size: 29.5 cm x 29.5 cm Detector matrix: 1943 x 1943 pixels DQE: 70% MTF > 50%@1lp/mm Pixel size 151.8 µm Gray scale 14bit	--	30 cm x 30 cm (12inch) (CMOS TFT technology) Size: 29.5 cm x 29.5 cm Detector matrix: 1943 x 1943 pixels DQE: 70% MTF > 50%@1lp/mm Pixel size 151.8 µm Gray scale 14bit	Same

Similar Detector/Technology Models used in 510(k) cleared devices.

	Similar Detector Models used in 510(k) cleared device/s			
Detector TFT Technology	**Subject Detector** **Skan C Pulsar**	**K181560** **Cios Alpha**	**K200218** **Digiscan FDX**	**K230871** **Extron 5/7**
CMOS	Xineos-2222HS	Xineos-2222HS		
	Xineos-3030HS	Xineos-3030HS		
aSi	Pixium 2121S-AU		Pixium 2121S-AU	
	Pixium 3030S-AU		Pixium 3030S-AU	
	Similar Detector Technology used in 510(k) cleared device/s			
IGZO	FXDD-2323G			EXPD 2121P
	FXDD-3131G			EXPD 3030P

Discussion of similarities and differences:

The Subject Device, Skan C Pulsar, and its Predicate Devices have same Intended Use of providing fluoroscopic images of patients during diagnostic, surgical and interventional procedure or surgery or treatment.

The Subject Device and Predicate devices are comparable in terms of mobility, patient positioning, C-arm housing X-ray source and detector, a workstation to view the images. Skan C Pulsar provides display of images, saving patient data and transmitting images over the PACS system are same.

Skan C Pulsar and its predicates share similar system and sub-system design and operating principles. Minor differences like power output with predicate device shall not impact any safety concern nor usage of the device for similar applications.

Detector technology, which is comparable to already 510k cleared devices with minor differences in pixels and sizes, are addressed in the FDA Solid State Device Guidance Evaluation and found to be not impacting any safety or performance of Skan C Pulsar. Where applicable as in IGZO detectors, were evaluated under the clinical expert opinion method, to demonstrate adequate image quality for clinical purposes.

Overall, with the above analysis, it is deemed acceptable that the Skan C Pulsar is substantially equivalent to the predicate device in terms of its intended use, safety and effectiveness.

Performance Data:

SKAN C PULSAR is designed and manufactured under the established quality management system in compliance with the following international and FDA recognized consensus standards and FDA guidance document. Risk analysis, design requirement review, design verification, design validation was conducted. Predefined acceptance criteria were met, and the subject device is safe and effective as the predicate device.

Summary of non-clinical tests:

Testing is carried out for SKAN C PULSAR and it is meeting the applicable requirements of the standards mentioned below:

1. IEC 60601-1 Edition 3.2 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2 Edition 4.1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard
3. IEC 60601-1-3 Edition 2.2 - Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
4. IEC 60601-1-6 Edition 3.2 - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
5. IEC 60601-2-43 Edition 3.0 - Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
6. IEC 60601-2-54 Edition 2.0 - Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
7. IEC 60601-2-28 Edition 3.0 2017-06 - Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

8. IEC 62304 Edition 1.1 - Medical device software - Software life cycle processes
9. IEC 62366-1 Edition 1.1 - Medical devices - Part 1: Application of usability engineering to medical devices
10. IEC TS 60601-4-2 Edition 1.0 - Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
11. ISO 14971 Edition 3 - Medical devices - Application of risk management to medical devices
12. NEMA XR 27 Amendment 1-2013 - X-ray equipment for interventional procedures - User Quality Control Mode
13. IEC 61910-1 Edition 1.0 2014-09 - Medical electrical equipment - Radiation dose documentation - Part 1: Radiation dose structured reports for radiography and radioscopy

Following FDA guidance documents were used in this premarket notification submission:

1. The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff, 2014
2. Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff, 2016
3. Post market Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff, 2016
4. Pediatric Information for X-ray Imaging Device Premarket Notifications: Guidance for Industry and Food and Drug Administration Staff, 2017
5. Electromagnetic Compatibility (EMC) of Medical Devices: Guidance for Industry and Food and Drug Administration Staff, 2022
6. Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff, 2023
7. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff, 2023

The proposed **Skan C Pulsar** demonstrated substantial equivalence to the currently marketed and predicate device DR Tech Corporation, Model **Extron 5** / Extron 7 was demonstrated with the following attributes:

• Indications for use.

• Technological characteristics.

• Non-clinical performance testing; and

• Safety and effectiveness.

Furthermore, on the Solid-State Detector evaluation with reference to similar technology used in currently 510(k) cleared devices are mentioned below.

CMOS detectors used Xineos-2222HS and Xineos-3030HS utilizes the same design and technology used in currently marketed and cleared device “Cios Alpha” with 510(k) number K181560.

Amorphous Silicon (AsI) detectors Pixium 2121S-AU and Pixium 3030S-AU utilizes the same design and technology with minor changes in Pixel and panel size used in the currently marketed and cleared device is being used in “Digiscan FDX” with 510(k) approval K200218.

IGZO detectors FXDD-2323G and FXDD-3131G utilizes similar design and technology with minor changes in size and specifications used in the currently marketed and 510(k) cleared devices like DRTech Corporation, Extron5/Extron7 with 510(k) number K230871.

All technical detector characteristics that potentially have an influence on image quality are assessed and verified according to “FDA Guidance for Industry and Food and Drug Administration Staff: Guidance for the Submission of 510(k)’s for Solid State X-ray Imaging Devices”; issued on September 1, 2016.

For the detectors using IGZO technology FXDD-2323G and FXDD-3131G are further evaluated through clinical considerations under the qualified expert opinion methodology to substantiate the image quality, safety and performance of Skan C Pulsar.

Conclusion:

Based on the above details, SKAN C PULSAR is safe and effective when the device is used as labelled and is substantially equivalent to the currently marketed predicate device Extron 5.