October 27, 2023

Skanray Technologies Limited
Vasundhara R
Regulatory Head
Plot#15-17, Hebbal Industrial Area
Mysore, Karnataka 570016
INDIA

Re: K231761
Trade/Device Name: PodSKAN HF Diagnostic X-ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: June 16, 2023
Received: June 16, 2023

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.

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,

Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological 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)*
K231761

Device Name

PodSKAN HF Diagnostic X-ray System

Indications for Use *(Describe)*

PodSKAN HF Diagnostic X-Ray System is intended for use by the qualified and trained clinicians or radiographers for generating X-rays of feet. It can be used for adults and paediatrics.

PodSKAN is not intended for Mammography and Fluoroscopy 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.

510(k) Summary

510(k) summary of safety and effectiveness for PodSKAN HF Diagnostic X-ray system is provided in accordance with 21 CFR 807.92

Date:	10th June 2023
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:	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
Device Trade Name:	PodSKAN HF Diagnostic X-ray system
Regulation Number:	892.1680
Regulation Name:	Stationary X-ray system
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: **Reference Device:**	• HF 718BD X-Ray System (K160857) Regulation number: 21 CFR 892.1680 Regulation name: Stationary X-ray system Device class: II Product code: KPR Review panel: Radiology • Televere Podiatry X-Ray System HF (K180765) Regulation number: 21 CFR 892.1680 Regulation name: Stationary X-ray system Device class: II Product code: KPR Review panel: Radiology

Device Description

PodSKAN is an advanced high frequency type X-Ray system designed for superior image quality with powerful 2.8KW generator and very low leakage radiation. The system houses two microprocessors, one for control/supervisory functions and another one man-machine/User interface. It can be easily plugged into 16A wall socket with 120 VAC or 240 VAC, 50/60 Hz. The technology incorporates feedback circuits to ensure highest accuracy & reproduceability of X-Ray output. It consists of

- Tube head assembly (including collimator and goniometer)
- Base foot platform and side handle for patient support
- External console and Hand switch

PodSKAN HF diagnostic X-ray system 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 flat panel detectors with AED functionality wired or wireless of size 10”x12” or 14”x17”and image acquisition systems to maintain compliance and quality

Intended Use / Indications for Use

PodSKAN HF Diagnostic X-Ray System is intended for use by the qualified and trained clinicians or radiographers for generating X-rays of feet. It can be used for adults and paediatrics.

PodSKAN is not intended for Mammography and Fluoroscopy Applications.

Comparison to predicate and reference devices

One predicate device and one reference device is selected in this submission for the PodSKAN HF Diagnostic X-ray system.

Predicate device : HF 718BD X-ray Ray System (K160857)

Reference device: Televere Podiatry X-Ray System HF (K180765)

The image quality of X-ray system depends on two main factors - the X-Ray generation and the image acquisition system. The X-Ray voltage generator, the technology, design of the subject device is substantially equivalent to the predicate device, with 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 PodSKAN HF Diagnostic X-ray System include film, computed radiography and digital radiography.

The details of the substantial equivalence between the subject device, predicate device and reference device are explained in the table below.

Comparison to Predicate and Reference devices

Comparable Properties	Subject Device	Predicate Device	Reference Device	Comparison results
MAKE	Skanray Technologies Limited	X-Cel X-Ray Corporation	Televere Systems	-
MODEL	PodSKAN HF Diagnostic X-Ray System	HF 718BD X-Ray System	Televere Podiatry X-Ray System HF	-
Regulation number	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680	Identical
Regulation name	Stationary x-ray system	Stationary x-ray system	Stationary x-ray system	Identical
Product code	KPR	KPR	KPR	Identical
Regulatory Class	Class II	Class II	Class II	Identical
FDA 510k number	-	K160857	K180765	-
Indications for use	PodSKAN HF Diagnostic X-Ray System is intended for use by the qualified and trained clinicians or radiographers for generating X-rays of feet. It can be used for adults and paediatrics. PodSKAN is not intended for Mammography and Fluoroscopy Applications.	The HF 718BD X-ray System is intended for use by qualified clinicians for the x-ray of hands and feet.	The Televere Podiatry X-Ray System HF is intended for use by qualified clinicians for the x-ray of hands and feet. Not for mammography. Not fluoroscopy.	Substantially Equivalent. PodSKAN HF covers the same indication for feet as compared to the predicate device but excludes the hand anatomy. Safety and effectiveness of the system remains same as compared to the predicated device for x-ray of feet.
Generator Type	High Frequency	High Frequency	High Frequency	Identical

kVp Range	40-80 kV in Steps of 2kV	50kV to 90kV +/- 10% adjustable in 2 kV steps	Adjustable kilo-voltage from 50 to 90 kV	Substantially Equivalent. kV is termed as quality of X-ray which determines the penetrating power with optimum contrast. Minor range difference shall not impact the clinical image quality because user need to select appropriate technique parameter (kV & mAs) for the subjective anatomy. Settings are however, allowed to the user to set as needed clinically.
mA Range	10mA-60mA	Fixed at 10mA +/- 1%	X-ray tube current 10 mA fixed	Substantially Equivalent. As compared to the predicate device. Skanray podiatry includes 10mA in its user controlled parameter with extended mA range for any clinical need by the user
mAs Range	0.32 mAs-16mAs in 23 Steps	Exposure times from 50 to 500 mS Adjustable kilo-voltage from 50 to 90 kV No automatic exposure control or mAs settings	Exposure times from 50 to 500 mS Adjustable kilo-voltage from 50 to 90 kV No automatic exposure control or mAs settings	Substantially Equivalent. Device support preset mAs range for the needed clinical purpose. With extended mA range and time creating similar combination as predicate device.
Configuration	X-ray generator	X-ray generator and Software only. No digital flat panel	X-ray generator and Software only. No digital flat panel	Substantially Equivalent. X-Ray Generator and it can be used with any approved software and digital flat panel having AED functionality
Focal Spot	Stationary anode :1.2mm as per IEC 60366	Stationary anode Focal spot 1.0 mm NEMA	Stationary anode Focal spot 1.0 mm NEMA	Substantially Equivalent. 1.0 to 1.2mm focal spots are usually used for stationary x ray tubes other than mammography. Clinically not much difference in quality and sharpness.

Half Value Layer	3.619mm Al @80kV	3.31mm Al @90kV	3.31mm Al @90kV	Substantially Equivalent. Meet the 21CFR1020.30(m) Half value layer requirements
Mains Voltage Range and Frequency	100-240V AC RMS @50-60Hz	105-130 volt AC @ 58-62Hz. Single phase. Less than 20 Amperes.	105-130 volt AC @ 58-62Hz. Single phase. Less than 20 Amperes.	Substantially Equivalent. meets predicate device input voltage range.
Exposure switch	Deadman switch	Deadman switch	Deadman switch	Identical
Exposure Control	Manual Touchscreen	Manual Touchscreen	Tigerview Software	Identical
Goniometer	Yes	Yes	Yes	Identical
Performance Accuracy	21 CFR 1020.31 compliant	21 CFR 1020.31 compliant	21 CFR 1020.31 compliant	Identical
kV accuracy	+/- 5%	+/- 8%	+/- 8%	Better. Substantially Equivalent
Electrical Safety & EMC	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Identical
Product Type	Fixed X-Ray Machine	Fixed X-Ray Machine	Fixed X-Ray Machine	Identical
Collimator Type	Fixed	Fixed	Fixed	Identical
Collimator lamp timer	30 seconds	13 seconds	13 seconds	Substantially Equivalent. Function is available. Timing does not impact indicated application, as this is used to visually ensure the x-ray'ed region

Exposure Presets	11 positions in APR chart	14 - For repeatedly used techniques	37 total (Ankle 10, Foot 9, Calcaneus 9, Other 9)	Substantially Equivalent. APR chart available for various anatomical positions, similar to the predicate.
Source to Image Receptor Distance	32.7" inch	29" inches	29" inches	Substantially Equivalent. Source to image receptor is a distance selected from engineering perspective for the X-Ray area to be covered, depends on the Anode angle of the tube. This does not impact the performance and intended application of the device

Discussion of similarities and differences

PodSKAN HF Diagnostic X-Ray System is intended for use by the qualified and trained clinicians or radiographers for generating X-rays of feet. It can be used for adults and paediatrics.

PodSKAN is not intended for Mammography and Fluoroscopy Applications.

Predicate, Reference and subject device are stationary x-ray system covering the similar anatomy as indicated in the comparison table above. kV & mAs minor range difference shall not impact the clinical image quality because user need to select appropriate technique parameter for the subjective anatomy. Settings are however, allowed to the user to set as needed clinically. The controls of the subject device is either identical or similar to predicate devices. The other components like the Basefoot platform and handles provided for patient support have no impact on the safety and effectiveness of the system.

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.

PodSKAN HF Diagnostic X-ray system complies with the following standards.

1.IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 - General requirements for basic safety and essential performance

2. IEC 60601-2-28:2010 Ed 2.0 Medical electrical equipment- Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

3. IEC 60601-2-54:2009+Amd1-2015+Amd 2-2018 Ed 1.2 Medical electrical equipment- Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

4. IEC 60601-1-3 :2008 +Amd 1-2013 Ed 2.1Medical electrical equipment -Part 1: General requirements for safety - Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment

5. IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 Ed 3.2 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral 8standard: Usability.

6. IEC 62366-1:2015+AMD1:2020 Ed 1.1 Medical devices- Application of usability engineering to medical devices

7. IEC 62304:2006+AMD1:2015 Ed 1.1 Medical device software – Software life-cycle processes

8. ISO 10993-1:2018 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.

9. 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

10. FDA Performance standards 21 CFR 1020.30-Diagnostics X-Ray system and their major components and 21 CFR 1020.31-Radiographic equipment.

11. BS EN ISO 15223-1:2021: Symbols for use in the labeling of medical devices- for Manufacturer, Date of Manufacture, Serial Number, and Part/Model Number.

12. EN ISO 14971:2019 Medical devices – Application of Risk Management to medical devices.

FDA guidance documents used in the development of PodSKAN HF Diagnostic X-ray System

1. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff, October 2014

2. Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Draft Guidance for Industry and Food and Drug Administration Staff, April 2022

3. Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff , November 28, 2017

4. Postmarket Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff

5. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

6. The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff

Summary of Non-Clinical Testing.

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 as per IEC 60601-2-54, 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. The device also complies with FDA

performance standards 21CFR 1020.30-1020.31. The validation testing, which includes sample clinical images, demonstrates compliance to the diagnostic quality imaging performance when used with 510k cleared detector and imaging software for the intended application.

Summary of Clinical Testing:

Subject device has substantial similarities when compared to the predicate devices.

Since the clinical application remain same as of predicate device/s, Non-clinical data is considered sufficient to demonstrate safety and performance of PodSKAN HF Diagnostic X-ray System, Clinical studies are not deemed necessary.

Conclusion:

Above details collectively demonstrate that PodSKAN HF Diagnostic X-ray System is safe and effective when the device is used as labelled and is found substantially equivalent to the predicate device.