April 19, 2022

XERA Medical Systems & Technology Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave STE 160
IRVINE CA 92612

Re: K220149
Trade/Device Name: GR10X-40K
GR10X-50K
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: January 17, 2022
Received: January 19, 2022

Dear Priscilla Chung:

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)*
K220149

Device Name
GR10X-40K
GR10X-50K

Indications for Use *(Describe)*
The GR10X Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This system is 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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510(k) Summary

[As required by 21 CFR 807.92]

This 510(k) summary information is prepared in accordance with 21 CFR807.92.

1. Date Prepared [21 CFR 807.92(a) (1)]

4/12/2022

2. Submitter's Information [21 CFR 807.92(a) (1)]

Name of Sponsor:	Xera Medical Systems and Technology Ltd.
Address:	Gulden Sk. 13/2 Kavaklidere, Ankara, Turkey
Contact Name:	Oh, Kevin / Regulatory Affairs Associate
Registration Number:	3006013411
Name of Manufacturer:	Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

Trade Name:	OCTAVE
Model Name:	GR10X-40K, 50K
Common Name:	General Radiography X-ray System
Classification Name:	System, X-Ray, Stationary
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1680
Product Code:	KPR
Device Class:	2

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

510(k) Number:	**K081722**
Product Code:	KPR
Applicant:	SIEMENS MEDICAL SOLUTIONS USA, INC.
Trade Name:	Ysio
Decision Date:	03/15/2018
Type:	Traditional

5. Description of the Device [21 CFR 807.92(a) (4)]

This device consists of X-ray control, high-voltage generator, X-ray tube, X-ray tube support, irradiation equipment, detectors, patient table, patient photography stand, digital imaging device, viewer SW, etc. The detectors and the viewer SW are cleared under the following 510ks.

- VIVIX-S VW(K200418)
  Model Names: FXRD-2530VW, FXRD-2530VW PLUS, FXRD-3643VW, FXRD-3643VW PLUS, FXRD-4343VW, FXRD-4343VW PLUS, with imaging areas of 25cm x 30cm, 36cm x 43cm, 43cm x 43cm, respectively.

A high frequency inverter (Inverter) X-sensor voltage device designed to generate X-rays by combination of tube voltage, tube current, irradiation time, etc. so that it can be filmed at various angles for diagnosis of the patient's skeletal, respiratory, and urinary systems. The digital imaging system is used to obtain the images taken by the X-ray unit as radiation from the X-ray unit passes through the human body and is transmitted by the detector. The detector intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo (a-SI)-detectors that create electrical signals. After the electrical signals are generated, it is converted to digital value, and the Software, VXvue, acquires and processes the data values from the detector. The resulting digital images will be displayed on monitors.

6. Indications for Use [21 CFR 807.92(a)(5)]

The GR10X Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This system is not intended for mammographic applications.

7. Technological Characteristics [21 CFR 807.92(a) (6)]

Comparisons with the predicate, the system shows the technological characteristics of the proposed GR10X-40K, 50K device to be substantially equivalent to the predicate devices. The proposed devices are functionally identical to the predicate devices.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate devices (K081722), the GR10X-40K has the subsequently equivalent:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Communication Method

There is no significant difference between the GR10X Digital X-ray Imaging System and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, operational principles and intended use.

Table 1: Comparison of Subject Device GR10X-40K, 50K to the Predicate

	Predicate Device	Subject Device	
Feature	Ysio	GR10X-40K	GR10X-50K
Indications for Use	The Ysio (New RAD -FAMILY) systems are radiographic systems used in hospitals, clinics, and medical practices. Ysio enables radiographic and tomographic exposures of the whole body including: skull, chest, abdomen ,and extremities and may be used on pediatric, adult and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critical ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Ysio system is not meant for mammography. The Ysio uses an integrated or portable digital detector for generating diagnostic images by converting x-rays into electronic signals. Ysio is also designed to be used with conventional film/screen or Computed Radiography(CR) cassettes.	The GR10X Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. This system is not intended for mammographic applications.	

Table 2: Comparison of Subject Device GR10X-40K, 50K to the Predicate

	Predicate Device	Subject Device		
Feature	Ysio	GR10X-40K	GR10X-50K	Comparison Results
Technical Comparison				
X-ray				
Generator	Polydoros 65/80 kW	DMG-40KAX A	DMG-50KAX B	Substantially Equivalent
X-ray tube	OPTITOP 150/40/80/HC-100	E7239X	E7252X	
Collimator	Collimator N	M38		
X-ray techniques	Radiography	Radiography		
Organ programs	X-ray parameters Imaging processing parameters	X-ray parameters Imaging processing parameters		
Testing				

IEC Compliance	IEC 4th edition for EMC testing	IEC 4th edition for EMC testing	Testing according to current IEC test scope
Digital Imaging			
SSXI for Rad imaging	Trixell Pixium MAX wi-D = 3543EZh MAX mini = 2430EZ MAX Static = 4343RC	VIVIX-S 4343VW, VIVIX-S 3643VW, VIVIX-S 2530VW, VIVIX-S 1717V	Substantially Equivalent

Table 3: Comparison of VIVIX-S VW Series and VIVIX-S 1717V to the predicate Trixell Pixium 4343RCE to the predicate Trixell Pixium 4343RCE

Technical Specifications	Trixell Pixium 4343RCE detector	VIVIX-S VW Series, VIVIX-S 1717V (Subject)	Comparison Results
Dimensions	423.3mm x 425.4 mm	VIVIX-S 4343VW: 460 mm x 460 mm VIVIX-S 3643VW: 384㎜ × 460㎜ VIVIX-S 2530VW: 287mm x 350mm VIVIX-S 1717V: 460mm x 460mm	Substantially Equivalent
Resolution	2860 x 2874 pixels	VIVIX-S 4343VW: 3072 x 3072 pixels VIVIX-S 3643VW: 2560 x 3072 pixels VIVIX-S 2530VW: 2048 x 2560 pixels VIVIX-S 1717V: 3072 x 3072 pixels	Substantially Equivalent
Pixel size	148 µm	VIVIX-S 4343VW: 140㎛ VIVIX-S 3643VW: 140㎛ VIVIX-S 2530VW: 124㎛ VIVIX-S 1717V: 140㎛	Substantially Equivalent
Semiconductor Material	Amorphous silicon, a-Si	Amorphous silicon, a-Si	Substantially Equivalent
Scintillator	Cesium iodide (CsI)	Cesium iodide (CsI), Gadolinium Oxide(Gadox)	Substantially Equivalent
Acquisition depth	16 bit	16 bit	Substantially Equivalent

DQE (Detective Quantum Efficiency)	DQE @ 0.05 lp/mm (2 µGy), 67%	FXRD-4343VAW: 47% FXRD-4343VAW PLUS: 62% FXRD-3643VAW: 45.5% FXRD-3643VAW PLUS: 61% FXRD-2530VAW: 49% FXRD-2530VAW PLUS: 61% FXRD-1717NAW: 50% FXRD-1717NBW: 27%	Substantially Equivalent
MTF (Modulations transfer function)	MTF @ 1 lp/mm, 62%	FXRD-4343VAW: 76% FXRD-4343VAW PLUS: 60% FXRD-3643VAW: 74% FXRD-3643VAW PLUS: 61% FXRD-2530VAW: 76% FXRD-2530VAW PLUS: 60% FXRD-1717NAW: 66% FXRD-1717NBW: 58%	Substantially Equivalent

9. Summary of Non-Clinical Data

A comparison test was conducted between the subject devices and the predicate device (K081722) on the items such as DQE, MTF and spatial resolution.

These detectors comply with the following international and FDA-recognized consensus standards:

- 21CFR1020.30, Diagnostic X-ray Systems, and their major components
- 21CFR1020.31, Radiographic equipment
- IEC 60601-1 Medical Electrical Equipment -- Part 1: General Requirements for Basic Safety and Essential Performance.
- CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Equipment –Part 1 : General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada)

- ANSI/AAMI ES60601-1 (2005+ C1:09+A2:10) (Medical Electrical Equipment – Part 1
- IEC 60601-1-2 Medical Electrical Equipment - Part 1-2
  : General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests

We also referenced the following FDA guidance:

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014
- Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software contained in Medical Devices, Document issued on: May 11, 2005 Medical Devices, Document issued on: May 11, 2005
- Guidance for Industry and Food and Drug Administration Staff Pediatric Information for X-ray Imaging Device Premarket Notifications, November 2017

10. Summary of Clinical Data

A single-blinded concurrence study was conducted, and the study confirmed that the GR10X Digital X-ray Imaging System provides images of equivalent diagnostic capability to the predicate devices, the Yiso and its results demonstrate substantial equivalence.

11. Conclusion [21 CFR 807.92(b) (3)]

The GR10X Digital X-ray Imaging System is substantially equivalent to the currently marketed and predicate devices (K081722) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Additionally, Substantial equivalence was demonstrated through the non-clinical performance, which complied with the requirements specified in the international and FDA-recognized consensus standards, IEC60601-1, IEC 60601-1-2, 3 and the clinical test.
The results of these tests demonstrate that GR10X Digital X-ray Imaging System meets the acceptance criteria and is adequate for this intended use. The comparison of technological characteristics, non-clinical performance data, safety testing, and clinical image concurrence data demonstrates that the device is as safe, as effective, and performs as well the predicate devices.