May 13, 2022

Radisen Co., Ltd.
% Mr. Dave Kim
President
Mtech Group
7505 Fannin St., Suite 610
HOUSTON TX 77054

Re: K221144
Trade/Device Name: PEDRA-1417 (Models: PEDRA-1417MC, PEDRA-1417MG
PEDRA-1417FC, PEDRA-1417FG
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: April 15, 2022
Received: April 20, 2022

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT 8B: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221144

Device Name
PEDRA- 1417 (Models: PEDRA-1417MC / PEDRA-1417MG
PEDRA-1417FC / PEDRA-1417FG)

Indications for Use *(Describe)*

The PEDRA Digital Flat Panel X-ray detector is indicated as a digital imaging solution designed for the general radiographic system for human anatomy. It is intended to replace film or screen-based radiographic systems in all general-purpose diagnostic procedures. It is not to be used for mammography.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
K221144

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date 510K summary prepared : May 2, 2022

Submitter's Name, Address, telephone number, a contact person:

Submitter's Name : Radisen Co., Ltd.
Submitter's Address: 14F, 128, Gongduk B/D, 11, Saechang-ro, Mapo-gu, Seoul, 04168, Republic of Korea
Submitter's Telephone: Tel:+82-31-8084-9762
Contact person: Mr.__John Lim____/ Director of DR Business Unit
Email Address: johnlim0107@radisentech.com

Official Correspondent: Dave Kim (davekim@mtech-inc.net)
Address: 7505 Fannin St. Suite 610, Houston, TX 77054
Telephone: +713-467-2607

Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Trade Device	PEDRA
Model Name	PEDRA-1417MC / PEDRA-1417MG PEDRA-1417FC / PEDRA-1417FG
Common Name	Digital Flat Panel X-ray Detector
Device Classification Name	Stationary X-ray System
Regulation Number	21 CFR 892.1680
Classification Product Code	MQB
Device Class	II
510(k) Review Panel	Radiology

Predicate Device

510(k) Number	K180989
Applicant	Radisen Co., Ltd
Trade/Device Name	PEDRA-17F (Model: PEDRA-17FC / PEDRA-17FG)
Common Name	Digital Flat Panel X-ray Detector
Classification Name	System, X-ray, Stationary
Regulation Number	21 CFR 892. 1680
Classification Product Code	MQB
Device Class	II
510(k) Review Panel	Radiology

Reference Device

510(k) Number	K181631
Applicant	Samsung Electronics Co., Ltd

Trade/Device Name	GR40CW (Model: S4335-W / S4335-WV)
Common Name	Digital Flat Panel X-ray Detector
Classification Name	System, X-ray, Stationary
Regulation Number	21 CFR 892. 1680
Classification Product Code	MQB
Device Class	II
510(k) Review Panel	Radiology

1. Device Description [21 CFR 807.92(a)(4)]

The PEDRA are wired or wireless digital flat panel detectors that have been designed for a faster, more streamlined approach to digital stationary X-ray systems. The PEDRA detector utilizes a combination of propriety TFT glass and scintillators (CsI / Gadox), and those and electronics are housed in one package. The detectors support an auto-trigger signal sensing technology that allows the detectors to be used without generator integration.
The flat panel sensors of the PEDRA are fabricated using thin-film technology based on amorphous silicon technology. Electronically, the sensors are much like conventional photodiode arrays. Each pixel in the array consists of a light-sensing photodiode and a switching Thin Film Transistor (TFT) in the same electronic circuit. Amorphous silicon photodiodes are sensitive to visible light, with a response curve roughly comparable to human vision. The sensitivity of amorphous silicon photodiodes peaks in green wavelengths, well-matched to scintillators such as CsI and Gadox. The response has the excellent linearity of a charge-integrating-biased photodiode.
SDK-Pedracalib(DMS) is the software of Detector that performs image acquisition, image correction, and pre-processing.

An x-ray generator (an integral part of a complete diagnostic x-ray system) is not part of this submission.

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

The PEDRA Digital Flat Panel X-ray detector is indicated as a digital imaging solution designed for the general radiographic system for human anatomy. It is intended to replace film or screen-based radiographic systems in all general-purpose diagnostic procedures. It is not to be used for mammography.

4. Summary of Design Control Risk management

The PEDRA detector has been developed to meet the critical functional requirements and international safety standards. The risks and the hazardous impact of the device design were analyzed with the FMEA method. The specific risk control and protective measures to mitigate the risks from the device design and production phase were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design and production were successfully mitigated and accepted.

5. Summary of the technological characteristics of the device compared to the predicate device:

The PEDRA detectors described in this 510(k) have similar indications for use and technical characteristics as the predicate device, S4335-W (of GR40CW) digital flat panel X-ray detector manufactured by Samsung Electronics Co., Ltd.

6. Substantial Equivalence [21 CFR 807.92(a)(6)]

There are no significant differences in the technological characteristics of these devices compared to the predicate device which adversely affects safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the PEDRA and the predicate device:

[Table 1. Comparison of Proposed Device to Predicate Devices]

Characteristic	Proposed Device	Predicate Device	Remark
510(k) number	K221144	K180989	
Manufacturer	Radisen Co., Ltd	Radisen Co., Ltd	
Trade Name	PEDRA (Model Name: PEDRA-1417MC / MG and PEDRA-1417FC / FG)	PEDRA-17F (Model Name: PEDRA-17FC / PEDRA-17FG)	
Common Name	Digital Flat Panel X-ray Detector	Digital Flat Panel X-ray Detector	Same
Product Code	MQB	MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
510(k) Review Panel	Radiology	Radiology	Same
Intended Use	The PEDRA Digital Flat Panel X-ray detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. It is not to be used for mammography.	The PEDRA-17F detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. It is not to be used for mammography.	Same
Scintillator	PEDRA-1417FC: CsI, Wired PEDRA-1417FG: Gadox, Wired PEDRA-1417MC: CsI, Wireless PEDRA-1417MG: Gadox, Wireless	PEDRA-17FG: Gadox :Tb PEDRA-17FC: CsI : TI	Same
Effective Pixel Area	350 x 427mm	432 x 432mm	Similarity
Total Pixel Number	2500 x 3052	3072 x 3072	Similarity
Pixel Pitch	140μm	140μm	Same
High Contrast Limiting Resolution	Max. 3.4 lp/mm	Max. 3.4 lp/mm	Same
Communication	Wired/Wireless	Wired	Different
Anatomical site	General	General	Same
Exposure Mode	Normal Mode(Manual), AED Mode (Auto Exposure Detection)	Normal Mode(Manual), AED Mode (Auto Exposure Detection)	Same

Table 2. Comparison of Proposed Device to the Reference Device

Characteristic	Proposed Device	Reference Device	Remark
510(k) number	-	K181631	
Manufacturer	Radisen Co., Ltd	Samsung Electronics Co., LTD	
Trade Name	PEDRA (Model Name: PEDRA-1417MC / MG and PEDRA-1417FC / FG)	GR40CW (Model Name: S4335-AW)	
Common Name	Digital Flat Panel X-ray Detector	Digital Flat Panel X-ray Detector	Same
Product Code	MQB	MQB	Same
Regulation Number	21 CFR 892.1680	21 CFR 892.1680	Same
510(k) Review Panel	Radiology	Radiology	Same
Intended Use	The PEDRA Digital Flat Panel X-ray detector is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic system in all general-purpose diagnostic procedures. It is not to be used for mammography.	The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screenfilm systems or CR systems may be used. This device is not intended for mammographic applications.	SE
Scintillator	PEDRA-1417FC: CsI, Wired PEDRA-1417FG: Gadox, Wired PEDRA-1417MC: CsI, Wireless PEDRA-1417MG: Gadox, Wireless	S4335-AW: CsI	Same
Effective Pixel Area	350 x 427mm	345 x 425mm	SE
Total Pixel Number	2500 x 3052	2,460 x 3,040	SE
Pixel Pitch	140μm	140μm	Same
High Contrast Limiting Resolution	Max. 3.4 lp/mm	Max. 3.57 lp/mm	SE
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	PEDRA-1417MC: 69%@0.1lp/mm	S4335-AW: 70%@0.1lp/mm	SE
MTF	PEDRA-1417MC: 96%@0.1lp/mm	S4335-AW: 95%@0.1lp/mm	SE
Anatomical site	General	General	Same
Exposure Mode	Normal Mode(Manual), AED Mode (Auto Exposure Detection)	Normal Mode(Manual), AED Mode (Auto Exposure Detection)	Same
Wireless	IEEE 802.11a/b/g/n	IEEE 802.11a/b/g/n	Same

The proposed device is substantially equivalent to the predicate device and the reference device as part of the complete imaging system.
It is substantially equivalent to these devices in design, function, materials, operational principles, and intended use. The proposed device, PEDRA has been tested for electrical safety, EMC, and performance, and the software has been validated.

The differences between the subject device and the predicate device are the size of the detector, and the availability of wireless module. The wireless module of the subject device is compared with the reference device. As a result of verification, it was confirmed that there is no difference in other performance. Therefore, the difference in the size of the detectors does not affect the safety and effectiveness. The wireless module performed substantially equivalently in comparison with the reference device.

These differences do not raise new questions of safety and effectiveness for the subject device.

7. Non-clinical test summary

The PEDRA complies with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The PEDRA complies with the electrical safety and electromagnetic compatibility requirements established by the standards

Standards No.	Standards Organization	Standard Title	Version	Publication Year
ES60601-1	AAMI ANSI	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD)	ES60601-1: 2005(R)201 2 and A1:2012	2014
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.0 2014-02	2015
-	FDA	Radio Frequency Wireless Technology in Medical Devices	August 14	2013

2) Software Validation The PEDRA contains a MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for the software contained in medical devices, on May 11, 2005

3) Performance Test Imaging performance test has been conducted according to:

- IEC 62220-1, Medical Electrical Equipment – Characteristics of Digital X-ray Imaging Devices – Part 1-1: Determination of the Detective Quantum Efficiency – Detectors Used in Radiographic Imaging. We select predicate device S4335-AW of GR40CW in order to demonstrate adequate DQE performance of the PEDRA detector. According to the above comparison table, the subject device shows similar or better DQE

4) Cybersecurity

- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, on October2, 2014

5) Label

- CFR Part 801
- Pediatric Information for X-ray Imaging Device Premarket Notifications, on November 28, 2017

8. Clinical Test Summary

Clinical data is not required to establish substantial equivalence based on the differences from the predicate (note TFT technology with CsI scintillator that is identical to the predicate image plate).

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

There are no significant differences between the PEDRA and the predicate device, K180989, and the reference device, K181631 that would adversely affect the use of the product.
It is substantially equivalent to these devices in indications for use and technology characteristics.

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

In according with the Federal Food & Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the PEDRA is substantially equivalent in safety and effectiveness to the predicate device and the reference device.