H&abyz
% Mrs. April Lee
Consultant
Withus Group, Inc.
106 Superior
IRVINE CA 92620

January 31, 2020

Re: K200018
Trade/Device Name: HAD1717MC
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: December 27, 2019
Received: January 3, 2020

Dear Mrs. Lee:

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,

For

Thalia T. Mills, Ph.D.
Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200018

Device Name
HAD1717MC

Indications for Use *(Describe)*
Digital Flat Panel X-ray Detector, HAD1717MC is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. This device 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary - K200018

Submitter

H&abyz
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Device Information

- Trade Name: HAD1717MC
- Classification Name: Stationary X-Ray System
- Common Name: Digital Flat Panel X-ray Detector
- Product Code: MQB
- Panel: Radiology
- Regulation Number: 892.1680
- Device Class: Class II
- Date prepared: 01/22/2020

Primary Predicate Device

- K number: K152094
- Trade Name: GR40CW
- Classification Name: Stationary X-Ray System
- Common Name: Digital Flat Panel X-ray Detector
- Product Code: MQB
- Panel: Radiology
- Regulation Number: 892.1680

Device Description

This is a wired digital flat panel x-ray detector, a fast and efficient digital radiography system. The detector is used in combination with a TFT glass and scintillator (CSI) and supports automatic trigger signal detection technology that can be used without generator integration.

The incident X-rays are converted into visible light that produces electron hole pairs in a photometer biased by scintillator material. The charge carrier is stored in the photodiode capacity. By pulse processing the gates of the TFT lines in the matrix, charges in all the columns are transferred in parallel with the signal output. All signals on the column are amplified by a custom Read Out IC for further processing.

The amplified signal is digitized using an A / D converter integrated into the ROIC. The digitized signal is transmitted to the PC. The device software is new software. When transferred to a PC, the software can acquire and store digitized images and view the images.

Indications for use

Digital Flat Panel X-ray Detector, HAD1717MC is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.

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Summary of Technological Characteristics

	Subject Device	**Primary Predicate**
Manufacturer	H&abyz	Samsung Electronics Co., Ltd.
510(k) Number	NA	K152094
Model	HAD1717MC	GR40CW
Indications for Use	Digital Flat Panel X-ray Detector, HAD1717MC is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.	The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.
Appearance		
Detector		
Panel Type	a-Silicon, TFT	a-Silicon, TFT
Scintillator	CsI	CsI
Detector Area	17 X 17 inches (427 x 427mm)	17 X 17 inches (425mm X 425mm)
Pixel Pitch (μm)	140	140
High Contrast Limiting Resolution(LP/mm)	3.5	3.5
DQE	TYP. 70% at 0.1 lp	TYP. 70% at 0.1 lp
MTF	TYP. 95% at 0.1 lp	TYP. 95% at 0.1 lp
Imaging Workstation		
CPU	Intel Core 2	Intel® Xeon® E5-1620
Memory (RAM)	4GB	8GB
Storage (HDD)	500GB	1TB
Monitor	1,920 x 1,080 pixels	21 inch (1,920 X1,080)
CIB(Control Interface Box)		
Max. Signal Input Voltage	N/A	400V DC/AC

Similarities	The subject and predicate devices are same and similar in indications, design, technology, functions, and principle of operation.	
Differences	Detector Area	As the imaging area and number of pixels is calculated by effective pixels, there may have some differences. However, this difference does not raise different questions of safety and effectiveness than the predicate.
	CPU	Subject medical device CPU has faster processing speed than the predicate device's CPU, and the faster processing speed does not contribute any adverse impacts to the device's safety and performance.
	Memory (RAM)	Subject medical device memory size is smaller than the predicate device's memory size, and the memory size does not contribute any adverse impacts to the device's safety and performance.
	Storage (HDD)	Subject medical device Storage has smaller capacity than the predicate device's Storage, and the small capacity does not contribute any adverse impacts to the device's safety and performance.
	Max. Signal Input Voltage	Subject medical device uses the TRIGGER line instead of the CIB. The CIB is managed by the x-ray system. The CIB only carries the signal, and the HAD1717MC's Trigger cable also carries the signal. Therefore, this difference does not raise different questions of safety and effectiveness than the predicate.

Non-clinical Testing

1) Electrical Safety and Electromagnetic Compatibility
Electrical, mechanical, environmental safety and performance testing were conducted according to standard ES 60601-1(2006/A1:2013), and EMC testing was conducted according to IEC 60601-1-2(2015). All test results were satisfying with the standards.

2) Performance data
Non-clinical testing data was provided in conformance to the FDA "Guidance for the Submission of 510(k)'s for Solid-State X-ray Imaging Devices", which includes MTF and DQE measurements as tested by IEC 62220-1. All test results were satisfying with the IEC62220-1 standards.

Clinical Data

In clinical data, clinical images were obtained in accordance with FDA guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices. The study confirmed that the subject x-ray detector provides images of equivalent diagnostic capability to the predicate device and its results demonstrate similar equivalence or slightly better.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification H&abyz concludes that Digital Flat Panel X-ray Detector is similar equivalent in comparison with the predicate device as described herein.