March 6, 2023

H&abyz Co., Ltd.
% Sanglok Lee
Manager
Wise Company, Inc.
#507, #508, 166 Gasan digital 2-ro
Geumcheon-gu, Seoul 08503
KOREA

Re: K223930
Trade/Device Name: A1417MCW/A1717MCW/F1417MCW
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: December 30, 2022
Received: December 30, 2022

Dear Sanglok 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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)*
K223930

Device Name
A1417MCW / A1717MCW / F1417MCW

Indications for Use *(Describe)*
A1417MCW / A1717MCW / F1417MCW (Digital Flat Panel X-Ray Detector) are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. 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

K223930

[As Required by 21 CFR 807.92]

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

March 3, 2023

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

- Name of Manufacturer: H&abyz Co. Ltd.
- Address: 1F, 2-Dong, 41-16 Cheoinseong-Ro, Namsa-Myeon, Cheoin-Gu, Yongin-Si, Gyeonggi-Do, Republic of Korea [17118]
- Contact Name: Namkyu Hur / Quality Manager
- Telephone No.: +82 070-4658-9300
- Email Address: hnk@abyzr.com
- Registration No.: 3016674851

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

Trade/Device/Model Name	A1417MCW/A1717MCW/F1417MCW
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

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

The identified predicate device within this submission is shown as follow;

Predicate Device

- 510(k) Number: K213497
- Applicant: H&abyz Co., Ltd.
- Detector Name: HAD1417MCW, HAD1717MCW
- Common Name: Digital Diagnostic X-ray System
- Classification Name: Stationary x-ray system
- Regulation Number: 21 CFR 892.1680
- Classification Product Code: MQB
- Device Class: II
- 510(k) Review Panel: Radiology

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

The A1717MCW/A1417MCW/F1417MCW is wired or wireless digital flat panel detectors that have been designed for faster, more streamlined approach to digital radiography systems. The A1717MCW/A1417MCW/F1417MCW detector utilize a combination of propriety TFT and scintillator (CsI), 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 A1717MCW/A1417MCW/F1417MCW 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. The response has the excellent linearity of a charge-integrating-biased photodiode.

SDK-MCW is the software of Detector that performs image acquisition, image correction, and pre-processing. According to the FDA guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," it has a moderate level of concern. Also, it does not base on previously-cleared software and was originally coded.

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

A1417MCW / A1717MCW / F1417MCW (Digital Flat Panel X-Ray Detector) are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.

7. Technological Characteristics (Equivalence to Predicate Device) [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 affect safety or effectiveness. Provided below is a table summarizing and comparing the technological characteristics of the A1717MCW/A1417MCW/F1417MCW and the predicate device:

[Table 1. Comparison of Proposed Device(A1717MCW) to Predicate Devices]

	Proposed Device	Predicate Device	Note
K Number	-	K213497	-
Manufacturer	H&abyz Co., Ltd.	H&abyz Co., Ltd.	-
Detector Name	A1717MCW	HAD1717MCW	-
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
Indications for Use	A1417MCW / A1717MCW / F1417MCW (Digital Flat Panel X-Ray Detector) are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	ADD (Digital Flat Panel X-Ray Detector) is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	Same

	Proposed Device	Predicate Device	Note
Scintillator	CsI	CsI	Same
Effective Pixel Area	425.04 x 425.6 mm	425.04 x 425.6 mm	Same
Total Pixel Number	3,072 x 3,072 pixels	3,072 x 3,072 pixels	Same
Pixel Pitch	140um	140um	Same
High Contrast Limiting Resolution (LP/mm)	Max. 3.57	Max. 3.5	Difference[1)]
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	69% (0.5lp/mm, min.)	43.8% (0.5lp/mm, min.)	Difference[2)]
MTF	97% (0.1lp/mm, min.)	97% (0.1lp/mm, min.)	Same
Anatomical Sites	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/ac	IEEE 802.11a/b/g/n	Difference[3)]

[Table 2. Comparison of Proposed Device(A1417MCW) to Predicate Devices]

	Proposed Device	Predicate Device	Note
K Number	-	K213497	-
Manufacturer	H&abyz Co., Ltd.	H&abyz Co., Ltd.	-
Detector Name	A1417MCW	HAD1417MCW	-
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
Indications for Use	A1417MCW / A1717MCW / F1417MCW (Digital Flat Panel X-Ray Detector) are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	ADD (Digital Flat Panel X-Ray Detector) is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	Same
Scintillator	CsI	CsI	Same
Effective Pixel Area	345.24 x 425.6 mm	345.24 x 425.6 mm	Same
Total Pixel Number	2,560 x 3,072 pixels	2,560 x 3,072 pixels	Same

	Proposed Device	Predicate Device	Note
Pixel Pitch	140um	140um	Same
High Contrast Limiting Resolution (LP/mm)	Max. 3.57	Max. 3.5	Difference[4)]
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	69% (0.5lp/mm, min.)	44.6% (0.5lp/mm, min.)	Difference[5)]
MTF	97% (0.1lp/mm, min.)	97% (0.1lp/mm, min.)	Same
Anatomical Sites	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/ac	IEEE 802.11a/b/g/n	Difference[6)]

[Table 3. Comparison of Proposed Device(F1417MCW) to Predicate Devices]

	Proposed Device	Predicate Device	Note
K Number	-	K213497	-
Manufacturer	H&abyz Co., Ltd.	H&abyz Co., Ltd.	-
Detector Name	F1417MCW	HAD1417MCW	-
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
Indications for Use	A1417MCW / A1717MCW / F1417MCW (Digital Flat Panel X-Ray Detector) are indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	ADD (Digital Flat Panel X-Ray Detector) is indicated for digital imaging solution designed for providing general radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems. Not to be used for mammography.	Same
Scintillator	CsI	CsI	Same
Effective Pixel Area	345.24 x 425.6 mm	345.24 x 425.6 mm	Same
Total Pixel Number	2,560 x 3,072 pixels	2,560 x 3,072 pixels	Same
Pixel Pitch	140um	140um	Same
High Contrast Limiting Resolution	Max. 3.57	Max. 3.5	Difference[7)]

	Proposed Device	Predicate Device	Note
(LP/mm)			
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	71% (0.5lp/mm, min.)	44.6% (0.5lp/mm, min.)	Difference[8)]
MTF	98% (0.1lp/mm, min.)	97% (0.1lp/mm, min.)	Difference[9)]
Anatomical Sites	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/ac	IEEE 802.11a/b/g/n	Difference[10)]

No	Differences	Explanation
1, 4, 7	High Contrast Limiting Resolution	High contrast limiting resolution is the value at which the signal detects lines or holes at fine intervals that differ considerably from the background. This is the result value calculated by the pixel pitch value and does not contribute any adverse impact to the device's safety and effectiveness.
2, 5, 8	DQE	The detective quantum efficiency (DQE) is one of the fundamental physical variables related to image quality in radiography and refers to the efficiency of a detector in converting incident x-ray energy into an image signal. The new detectors are higher than that of predicate devices. These differences do not contribute any adverse impact to the device's safety and effectiveness.
3, 6 10	Wireless	This is related to the wireless standards applied to the product. This change does not contribute any adverse impact to the device's safety and effectiveness.
9	MTF	The modulation transfer function (MTF) describes the frequency behavior of the system and is a curve that has lower values for high frequencies which represent the small image structures. The proposed device(F1417MCW) is 98% (0.1lp/mm, min.) and the predicate device is 97% (0.1lp/mm, min.). These differences do not contribute any adverse impact to the device's safety and effectiveness.

8. Non-Clinical Test summary

The A1717MCW/A1417MCW/F1417MCW 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 A1717MCW/A1417MCW/F1417MCW 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)2012 and A1:2012	2014
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Safety – Collateral Standard:	60601-1-2 Edition 4.1	2020

		Electromagnetic Compatibility - Requirements and Tests	2014-02	
62220-1-1	IEC	Medical electrical equipment-Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging	62220-1-1 Edition 1.0 2015-03	2015

2) Software Validation

The A1717MCW/A1417MCW/F1417MCW contains 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 software contained in medical devices, on May 11, 2005

3) Biocompatibility

- ISO 10993-1 and series, biological evaluation of medical devices

4) 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 the predicate device in order to demonstrate adequate DQE performance of the A1717MCW/A1417MCW/F1417MCW detector. According to the above comparison table, subject device shows better DQE.

5) Cybersecurity

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

6) Label

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

9. Clinical Test Summary

Clinical data has been provided according to FDA guidance document “Guidance for the Submission of 510(k)s for Solid Sate X-ray Imaging Devices”. Clinical images were provided; these images were not necessary 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) but they provide further evidence in addition to the laboratory performance data to show that the subject digital detector works as intended

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

There are no significant differences between the A1717MCW/A1417MCW/F1417MCW and the predicate device, K213497 that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

11. 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 A1717MCW/A1417MCW/F1417MCW is substantially equivalent in safety and effectiveness to the predicate device as described herein.