November 15, 2021

H&abyz Co., Ltd.
% Hyunook (David) Han
Regulatory Affairs Manager
1F, 2-Dong, 41-16 Cheoinseong-ro Namsa-myeon, Cheoin-gu
Yongin-si, Gyeonggi-do 17118
REPUBLIC OF KOREA

Re: K213497
Trade/Device Name: ADD
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: August 21, 2021
Received: November 1, 2021

Dear Hyunook (David) Han:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213497

Device Name
ADD

Indications for Use *(Describe)*
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.

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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5. 510(K) Summary

K213497

510(k) Summary

[As Required by 21 CFR 807.92]
K213497

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

October 28, 2021

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: hho@abyzr.com
- Registration No.: 3016674851

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

Trade/Device/Model Name	ADD
Reference No.	HAD1417MCW, HAD1717MCW
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 are shown as follow;

Predicate Device

- 510(k) Number: K203188
- Applicant: H&abyz Co., Ltd.
- Trade/Device Name: ADD
- Common Name: Digital Diagnostic X-ray System
- Classification Name: System. X-ray, Stationary
- Regulation Number: 21 CFR 892.1680
- Classification Product Code: MQB
- Device Class: II
- 510(k) Review Panel: Radiology

These predicate devices have not been subject to a design-related recall

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

The ADD are wired or wireless digital flat panel detectors that have been designed for faster, more streamlined approach to digital radiography systems. The ADD detector utilize a combination of propriety TFT glass and scintillators(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 ADD 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)]

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. 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 ADD and the predicate device:

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

	Predicate Device	Proposed Device	Note
K Number	K203188	-	-
Manufacturer	H&abyz Co., Ltd.	H&abyz Co., Ltd.	-
Trade Name	ADD	ADD	-
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	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. 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. Not to be used for mammography	Same
Detector name	HAD1417MCW	HAD1417MCW HAD1717MCW	Difference
Scintillator	CsI	CsI	Same
Effective Pixel Area	[HAD1417MCW] 345.24 x 425.6 mm	[HAD1417MCW] 345.24 x 425.6 mm [HAD1717MCW] 425.04 x 425.6 mm	Difference
Total Pixel Number	[HAD1417MCW] 2,560 x 3,072 pixels	[HAD1417MCW] 2,560 x 3,072 pixels [HAD1717MCW] 3072 x 3,072 pixels	Difference
Pixel Pitch	140um	140um	Same
High Contrast Limiting Resolution (LP/mm)	Max. 3.5	Max. 3.5	Same

	Predicate Device	Proposed Device	Note
Communication	Wired/Wireless	Wired/Wireless	Same
DQE	50% (0.1lp/mm, min.)	50% (0.1lp/mm, min.)	Same
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	IEEE 802.11a/b/g/n	Same

The proposed device is substantially equivalent to the previously cleared detector provided 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 has been tested about electrical safety, EMC, and performance, and the software has been validated. Also, the clinical data has been provided to support the substantial equivalence to the predicate device.

The only difference is the size of the detectors, and it is a difference only in the area where the x-ray image can be taken. And a result of verification, it was confirmed that there is no difference in other performance. Therefore, the difference in the sizes of the detectors does not affect the safety and effectiveness. These differences do not raise different questions of safety and effectiveness than the predicate.

8. Non-Clinical Test summary

The ADD 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 ADD 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: Electromagnetic Compatibility - Requirements and Tests	60601-1-2 Edition 4.0 2014-02	2016
-	FDA	Radio Frequency Wireless Technology in Medical Devices	August 14	2013

2) Software Validation

The ADD 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 ADD detector. According to the above comparison table, subject device shows similar or same 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 ADD and the predicate device, K203188 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 the subject device is substantially equivalent in safety and effectiveness to the predicate device as described herein.