August 4, 2025

H&abyz Co., Ltd.
% Jimin Han
1F, 2-dong, 41-16 Cheoinseong-ro, Namsa-myeon, Cheoin-gu
YONGIN-SI, GYEONGGI-DO 17118
SOUTH KOREA

Re: K251223
Trade/Device Name: HnX-P1, HnX-PB
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: April 10, 2025
Received: July 2, 2025

Dear Jimin 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251223

Device Name
HnX-P1, HnX-PB

Indications for Use *(Describe)*
The portable x-ray system may be used for diagnostic imaging of body extremities.
- Not for mammography use
- This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submitter's Information

- 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: Jimin Han / RA Manager
- Telephone No.: +82 010 8450 6678
- Email Address: hjm@abyzr.com
- Registration No.: 3016674851
- Date Prepared.: April 10, 2025

2. Trade Name, Common Name, Classification

Trade/Device/Model Name	HnX-P1, HnX-PB
Common Name	Portable X-ray System
Device Classification Name	Mobile X-ray System
Regulation Number	21 CFR 892.1720
Classification Product Code	IZL
Device Class	II
510(k) Review Panel	Radiology

3. Identification of Predicate Device(s)

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

Predicate Device#1

- 510(k) Number: K182207
- Applicant: MinXray, Inc.
- Trade/Device Name TR90BH
- Regulation Name Mobile x-ray system
- Classification Name: System, X-ray, Mobile
- Regulation Number: 21 CFR 892.1720
- Classification Product Code IZL
- Device Class: II
- 510(k) Review Panel: Radiology

4. Description of the Device

This device is a battery-powered portable X-ray System, designed and manufactured by H&abyz. This portable radiographic system (Model: HnX-P1, HnX-PB) consists of an LCD display with up and down soft-keys for controlling kV, an X-ray generator (line-powered transformer), an X-ray tube assembly, a collimator and a cart. It can also use a stand instead of a cart. The HnX-P1 is used with a film-cassette or flat-panel detector. (The film-cassette or flat-panel detector, cart, and stand are not included in the basic components of the product.)

The major components of the X-ray main unit include handle, enclosure, main control panel, system control board, high-voltage tank, inverter, collimator (beam limiter), and system control software running on the system control board. The system control software is for real-time interaction and control with various circuit modules inside the X-ray generator. The software responds to user operations on the control panel. The user can adjust and control the kV and mAs parameters, and the software will display the parameters or directly load the APR parameters. The software loads the control data from X-ray output into the high-voltage generation control circuit of the system control board, and control the high-voltage tank to generate high-voltage to excite the X-ray tube inside to emit X-rays, control the switch of the collimator, and monitor the working status of the device, and control the display of the status indicators.

The system is for X-ray imaging and diagnosis in facilities with portable or fixing sites. The device can be used with an X-ray flat panel detector, a computer for receiving and detecting signal results and an image processing software. This portable X-ray System is designed for handheld or stand-mounted imaging.

5. Indications for use

The portable x-ray system may be used for diagnostic imaging of body extremities.
- Not for mammography use
- This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.

6. Comparison of technological characteristics with the predicate device

Item	Proposed Device	Predicate Device#1
K Number	K251223	K182207
Manufacturer	H&abyz Co., Ltd.	MinXray, Inc.
Trade/Device Name	HnX-P1, HnX-PB	TR90BH
Common Name	Portable X-ray system	Portable X-ray system
Product Code	IZL	IZL
Regulation Number	21 CFR 892.1720	21 CFR 892.1720
510(k) Review Panel	Radiology	Radiology
Indications for Use	The portable x-ray system may be used for diagnostic imaging of body extremities. - Not for mammography use - This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.	This is a portable X-ray system with following limitations of use: The device may be used for handheld diagnostic imaging of body extremities. The device may be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device may be used for stand mounted imaging of the chest when used without a grid. - Not to be used on bariatric patients,

Item	Proposed Device	Predicate Device#1
		unless imaging body extremities - Not for mammography use - This device is not intended to replace a stationary radiographic system, which may be required for full optimization of image quality and radiation exposure for different exam types.
Weight	3.5kg	7.5kgs
Size	293.4 x 151.8 x 256.5 mm	219 x 350 x 190 mm
Energy Source:	Li-Polymer Rechargeable Battery (29.6Vdc, 1,470mAh)	Lithium-ion Rechargeable Battery (57.6DC), 300 exposures per charge.
Use Interface	Soft touch push buttons	Soft touch push buttons
Exposure times:	sec: 0.040 ~ 2.000sec. 0.04, 0.05, 0.06, 0.075, 0.10, 0.125, 0.13, 0.16, 0.2, 0.25, 0.32, 0.40,0.5, 0.63, 0.8, 1.0, 1.25, 1.3, 1.6, 2.000 (20 Steps)	0.01 sec – 1.0 sec : 0.01 sec Step High Power Mode 0.01 sec – 0.3 sec : 0.01 sec Step
mA:	10mA (@50kV ~ 70kV), 8mA (@71kV ~ 90kV)	20 mA @ 40 kVDC – 60 kVDC (2 kVP steps) 15 mA @ 62 kVDC – 80 kVDC (2 kVP steps) 10 mA @ 82 kVDC – 90 kVDC (2 kVP steps) High Power Mode 15 mA @ 82 kVDC – 90 kVDC (2 kVP steps)
Memory settings (technique)	10 memories via APR mode	5 memories via pushbutton
HF Generator	High Frequency	High Frequency
kW	0.72kW	1.35 kW
kVp	50 – 90kVp	40 – 90kVp
X-ray Tube	OX/90	D-0814
FDA Performance Standard	Complies	Complies
Collimator	DEPS126001	Mikasa BLD34L
Photo	 [HnX-P1]	

Item	Proposed Device	Predicate Device#1
	 [HnX-PB]	

7. Non-Clinical Test summary

A total of 30 clinical image samples, including elbows, hands, knees, ankles, and feet, were reviewed by qualified clinicians and determined to be of good quality and clinically useful.

Software validation and risk analysis was performed.

Laboratory testing was performed according to the following standards:

Standards	Safety/EMC Standards Description	FDA Recognition No.
IEC 60601-1	Medical electrical equipment, Part 1: General requirements for basic safety and essential performance	19-49
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-36
IEC 60601-1-3	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	12-336
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-132
IEC 60601-2-28	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	12-309
IEC 60601-2-54	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	12-348
IEC 62304	Medical device software - Software life cycle processes	13-79
IEC 62366	Medical devices - Part 1: Application of usability engineering to medical devices	5-129
ISO 14971	Medical devices - Application of risk management to medical devices	5-125
ISO 15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5-134

1) Cybersecurity

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 27, 2023)

2) Label

- CFR Part 801

8. Clinical studies

Clinical studies were not performed.

9. Substantial Equivalence

There are no significant differences between the HnX-P1 and HnX-PB compared to the predicate device, K182207, that would adversely affect their intended use. They are substantially equivalent in terms of indications for use and technological characteristics.

10. Conclusion

In accordance with the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, we conclude that the HnX-P1 and HnX-PB are substantially equivalent in terms of safety and effectiveness to the predicate device described herein.