September 12, 2025

BONTECH Co., Ltd.
% Ki-Chan An
Regulatory Manager
Digital Empire D-building #1201~1203, 16, Deogyeong-daero
1556 beon-gil, Yeongtong-gu
Suwon-si, Gyeonggi-do 16990
SOUTH KOREA

Re: K243864
Trade/Device Name: Bonx805
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: August 2, 2025
Received: August 4, 2025

Dear Ki-Chan An:

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)*
K243864

Device Name
BONX805

Indications for Use *(Describe)*
The BONX805 is a portable X-ray system for diagnostic imaging of body extremities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

K243864

510(k) Summary

Date: 12 SEP. 2025

1. **Submitter name:** BONTECH Co., Ltd.
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   Contact person: Jua Kim, Regulatory Manager
   and e-mail address: kja@bontech1.com

2. **information of classification name for the device**
   Common name of the device : Portable X-Ray System
   Name of the device : BONX805

   Device: system, x-ray, mobile
   Regulation Description: Mobile x-ray system.
   Regulation Medical Specialty: Radiology
   Review Panel: Radiology
   Product Code: IZL
   Premarket Review: Office of Radiological Health (OHT8)
   Radiological Imaging Devices and Electronic Products (DHT8B)
   Regulation Number: 892.1720
   Device Class: II

3. **The reason for the 510(k).**
   The purpose of this traditional 510(k) is to obtain market clearance for the BONX805, a new device, based on the concept of substantial equivalence to a legally marketed device.

4. **Identification of the legally marketed device (predicate) to which you claim SE.**
   the 510(k) number for the predicate device: K212144
   trade name: Remex KA6
   product code: IZL

   Name: Mobile X-Ray System
   Regulation Name: Mobile X-Ray System
   Regulation Number: 21 CFR 892.1720
   Medical Specialty: Radiology
   Regulatory Class: II
   Submission Type: 510(k)

5. Device Description and Principles of Operation

A. Overview

BONX805 is portable X-ray unit integrated with small computer. BONX805 goes with you no matter where the patient is (hospitals, clinics, nursing home and out-of-office mobile use). One unit can serve all the operators in your practice. BONX805 was designed to help doctors and radiologists for exact diagnosis with clear X-ray images and safety from unnecessary radiation exposure. This device shall be used in professional healthcare environment. An x-ray detector (necessary component for a fully-functional diagnostic system) is not part of the device.
Basic functions of the subject device BONX805 are supported by software(firmware). The firmware of portable X-ray is a software which installed in product to operate BONX805. The firmware is installed in the hardware (embedded system). The firmware(Version: REV 1.00) controls the use mode and irradiation, also the firmware is expected to unchanged during its lifetime.

B. Intended use

Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

C. Principles of Operation

BONX805 generates and controls X-rays using the power of the built-in battery, and irradiation is absolutely prohibited during charging. X-ray irradiation is controlled by the designed electronic circuit and MCU, and among the conditions necessary for shooting, the tube voltage is adjustable and the tube current is fixed. The irradiation time is set manually, and the value adjusted by the MCU electronically controls the semiconductor switching element. Using this X-ray, it passes through the body part to be diagnosed to obtain an image with a detector so that it can be used for diagnosis. The irradiation time setting method sets the irradiation time by the user turning the dial manually.
After setting, press the exposure button.
The BONX805 should be used with an X-ray detector, and this detector has a digital type and a film type. But the X-ray detector is not included in the BONX805 package.

D. Indication for use

The BONX805 is a portable X-ray system for diagnostic imaging of body extremities.

6. Substantial Equivalence Comparison

Both the subject(BONX805) and predicate(Remex KA6) device are intended for mobile x-ray examination of adult and pediatric populations.

Both devices are DC-powered by battery while charged with AC-power.
Tube potential and mAs for the subject device are similar to those of the predicate device. The subject device has a fixed tube current of 2-5mA whereas the predicate device can vary between 2-6mA. Both exposure power settings are capable of producing diagnostic x-ray images of extremities for adult and pediatric patients.

Due to differences in technological characteristics (kV, exposure time, mA) between the target and predicate device, the predicate devices, Remex KA6, can produce slightly more X-ray exposure.

The above comparison of technological characteristics shows to be less powerful than the predicate, with lower tube voltage and current being the more obvious examples. These variations raise no new issues of safety or effectiveness.

Model name / Characteristic	BONX805	Remex KA6 (K212144)	Equivalence
Manufacturer	BONETECH Co., Ltd.	Remedi Co., Ltd	
Indication for Use	The BONX805 is a portable X-ray system for diagnostic imaging of body extremities.	The KA6 is a portable X-ray system for diagnostic imaging of body extremities.	Same
Intended use	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.	Same
Principles of Operation	BONX805 generates and controls X-rays using the power of the built-in battery, and irradiation is absolutely prohibited during charging. X-ray irradiation is controlled by the designed electronic circuit and MCU, and among the conditions necessary for shooting, the tube voltage is adjustable and the tube current is fixed. The irradiation time is set manually, and the value adjusted by the MCU electronically controls the semiconductor switching element. Using this X-ray, it passes through the body part to be diagnosed to obtain an image with a detector so that it can be used for diagnosis. The irradiation time setting method sets the irradiation time by the user turning the dial manually. After setting, press the exposure button. The BONX805 should be used with an X-ray detector, and this detector has a digital type and a film type. But the X-ray detector is not included in the BONX805 package.	REMEX-KA6 generates and controls X-rays using the power of the built-in battery, and irradiation is absolutely prohibited during charging. X-ray control is controlled by the designed electronic circuit and MCU, and among the conditions necessary for shooting, the tube voltage is from 40 kV to 70 kV and the tube current is from 2 mA to 6 mA. The irradiation time is from 0.06 s to 2.0 s, and the value adjusted by the MCU electronically controls the semiconductor switching element. Using this X-ray, it passes through the body part to be diagnosed to obtain an image with a detector so that it can be used for diagnosis. The irradiation time setting method sets the irradiation time by the user. After setting, press the shot button to perform investigation.	Same
Energy Source	22.2 V (Lithium Ion Polymer) 1450 mAh	22.2 Vdc, 1800 mAh Rated power of re-chargeable battery	Similar

Tube current (mA)	2 - 5mA (1 mA step)	2 - 6 mA (1 mA steps)	Similar
Tube potential (kV)	50 ~80 kV (1 kV step)	40 - 70 kVp (1 kVp steps)	Similar
X-ray exposure time range [sec]	0.03 ~ 0.20 sec (10 msec step) 0.20 ~ 2.00 sec (50 msec Step)	0.06 -2.0 sec (0.01 sec. steps)	Similar

7. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

A. Electrical Safety & Electromagnetic Compatibility(EMC)

- IEC 60601-1:2005/AMD2:2020
- IEC 60601-1-3:2008/AMD2:2021
- IEC 60601-1-6:2010, AMD1:2013, AMD2:2020 (IEC 62366-1:2015, AMD1:2020)
- IEC 60601-2-28:2017(X-Ray Tube)
- IEC 60601-2-54:2009/AMD2:2018
- EN 60601-1-2:2015 +A1:2021

B. Software

BONX805 completed software validation and was determined to be a basic level of concern software. The risk management test was performed in accordance with ISO 14971 and met all requirements of the standard. These tests were performed by the manufacturer and all requirements were met.

C. Bench Testing

Bench testing confirmed that the BonX805 image quality and generator safety meet international standards and show substantial equivalence to the predicate device. Tests were relevant protocols, with all results supporting regulatory compliance and effective performance. Overall, bench testing demonstrated suitability of BonX805 for its intended portable radiographic applications.

8. Conclusions

Comprehensive bench testing demonstrates that the BonX805 exhibits performance characteristics comparable to those of the predicate device, Remex KA6, as summarized below:

Image Quality Performance:
Detected Quantum Efficiency (DQE) measurements at key spatial frequencies, showed matching results. All observed differences are within the typical measurement uncertainty range (±3%), indicating no clinically meaningful deviation.

Spatial Resolution:
Both BonX805 and the predicate device demonstrate a maximum spatial resolution, supporting similar diagnostic performance.

Modulation Transfer Function (MTF):
The BonX805 performs equivalently to, and in some frequencies slightly better than, the predicate device, with MTF differences consistently below 1%.

Radiation Safety Compliance:
Radiation output and exposure parameters are within the applicable safety limits for both devices and align with the same regulatory standards.

Technological Comparison:
Both systems utilize comparable portable X-ray generator technologies and are intended for the same clinical indications (radiographic imaging of extremities).

Based on the measured performance characteristics, the BonX805 demonstrates equivalent diagnostic image quality and safety performance to the predicate device. These results support the determination of substantial equivalence for its intended use.