August 16, 2023

NEUF Inc.
% Yeonwoo Lee
Senior Staff
CTI co., Ltd
A-1712, 43, Iljik-ro
Gwangmyeong-si, Gyeonggi-do 14353
SOUTH KOREA

Re: K230581
Trade/Device Name: TOPA12 Portable X-ray Unit
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: July 3, 2023
Received: July 19, 2023

Dear Yeonwoo 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)*
K230581

Device Name
TOPA12 Portable X-ray Unit

Indications for Use *(Describe)*
The TOPA 12 Portable X-Ray Unit is intended for use by a qualified/trained doctor or technician on adult subjects for taking diagnostic radiographic exposures for acquiring X-ray images of the desired parts of patient anatomy of 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.

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510(k) Summary – K230581

I. SUBMITTER

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Date Prepared: May 12, 2023

II. DEVICE

Trade or Proprietary Name:	TOPA12 Portable X-ray Unit
Common or Usual Name:	Mobile X-ray System
Classification Name:	System, X-Ray, Mobile
Regulation Number:	892.1720
Regulatory Class:	II
Product Code:	IZL

III. PREDICATE DEVICE

510(k) Number:	K222896
Trade/Device Name:	AirRay
Product Name:	Diagnostic X-ray Unit
Model Name:	AirRay
Manufacturer:	POSKOM CO., LTD
Regulation Number:	892.1720

Regulatory Class: II

Product Code: IZL

IV. DEVICE DESCRIPTION

This portable radiographic unit (Model: TOPA12) consists of a LED display with up and down soft-keys for controlling kV, an X-ray generator (line-powered transformer), an X-ray tube assembly, a collimator. A cart or a stand can be used with the TOPA12. In addition, this unit has preset memory keys to store and select kV, The TOPA12 is used with a film-cassette or flat-panel detector.

This device is a mains-powered portable X-ray unit, designed and manufactured by NEUF.

Compared with traditional X-ray products, this device has exquisite structure, compact design, light weight and easy operation.

The major components of the X-ray main unit include: handle, enclosure, control panel, system control (SYS) board, high-voltage tank, collimator (beam limiter), and system control software running on the SYS board. The system control software is for real-time interaction and control with various circuit modules inside the portable X-ray unit. 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 indicator, 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 mobile or fixing sites.

Since the kV range of this device is 40~90kVp, which is not suitable for breast exams, the device is not intended for mammography.

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 unit is designed for handheld or stand-mounted imaging. This portable X-ray unit can be configured to an optional portable stand/rack or use a stand that complies with IEC 60601- 1 safety standard. The recommended maximum load that the stand can safely carry is 30kgs to ensure the mechanical stability and effectiveness of the device.

V. INDICATIONS FOR USE

The TOPA 12 Portable X-Ray Unit is intended for use by a qualified/trained doctor or technician on adult subjects for taking diagnostic radiographic exposures for acquiring X-ray images of the desired parts of patient anatomy of extremities.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	**Subject Device** TOPA12 Portable X-ray Unit 510(k) number : K230581	**Predicate Device** AirRay 510(k) number : K222896	
Indications for use	The TOPA 12 Portable X-Ray Unit is intended for use by a qualified/trained doctor or technician on adult subjects for taking diagnostic radiographic exposures for acquiring X-ray images of the desired parts of patient anatomy of extremities.	The POSKOM Portable X-ray unit is a device that can conveniently generate X-rays for diagnosis when the patient condition is difficult to move. Mainly used by trained specialists, doctors or radiologists. Indication: The POSKOM Battery Type Portable X-ray Unit is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the body parts. The device must be used for stand mounted diagnostic imaging of head, abdomen, or extremities. The device must be used for stand mounted imaging of the chest. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Contraindication: The use of X-radiation for diagnostic purposes in the following subjects is contraindicated. - Pregnancy, especially first trimester	Similar
Dimension	293×138×144mm	325 X 268 X 250 mm	Similar

Item	**Subject Device** TOPA12 Portable X-ray Unit 510(k) number : K230581	**Predicate Device** AirRay 510(k) number : K222896	
Weight	5.5kg	5.0kg	Similar
Output Power	1.2 kW	1.6kW	Similar
Energy source	25.2VDC 5000mAh	Lithium Polymer Battery 3.7V 5000mAh	Similar
Exposure times	0.04 sec – 2 sec	0.02 sec – 2 sec	Similar
Tube current	40kV ~ 50kV / 20mA / 0.4 ~ 20mAs 51kV ~ 60kV / 15mA / 0.4 ~ 16mAs 61kV ~ 70kV / 15mA / 0.4 ~ 16mAs 71kV ~ 80kV / 15mA / 0.4 ~ 3.2mAs 71kV ~ 80kV / 10mA / 4.0 ~ 20mAs 81kV ~ 90kV / 10mA / 0.4 ~ 20mAs	20mA (50 ~ 80kV / 0.4 ~3.2mAs) 10mA (50 ~ 70kV / 3.6 ~20mAs) 10mA (71 ~ 80kV / 3.6 ~16mAs) 15mA (81 ~ 90kV / 0.4 ~3.2mAs) 8mA (81 ~ 90kV / 3.6 ~16mAs)	Similar
Tube Voltage Range	40 – 90 kV	50 – 90 kVp	Similar
Memory settings	4 Memories	10 Memories	Different
HF Generator	High frequency	High frequency	Same
X-ray Tube	OX/80-0.8(CEI)	OX/70-1.0 (C.E.I.)	Different
Collimator	≥ 160 lx, max size 47 * 47 cm @ 1m	Double slit type and manually operation with LED Light indicator	Different
Product image			-

VII. PERFORMANCE DATA

Non-clinical testing

Sample clinical images of extremities (Elbow, Hand, Knee, Ankle, Foot) were reviewed by a qualified clinician, who found them to be of good quality and clinical utility.
Software validation and risk analysis was performed.
Laboratory testing was performed according to the following standards:

EN 60601-1:2006 /A1:2013/A12:2014/A2:2021 AAMI ES60601-1:2005, ES60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-3:2008 IEC 60601-1-3:2008/AMD1:2013 IEC 60601-1-3:2008/AMD2:2021	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010, AMD1:2013, AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-2-54:2009 +A1:2015+A2:2018	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy
IEC 60601-1-2:2014+A1:2020 IEC 60601-1-2:2015/A1:2021	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 62133-2:2017	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
IEC 62304:2006/AMD1:2016	Medical device software - Software life-cycle processes
IEC 62366-1:2015	Medical devices - Application of usability engineering to medical devices

Clinical studies

Clinical studies were not performed.

VIII. CONCLUSIONS

After analyzing bench tests, it is the conclusion of NEUF Inc. that the TOPA12 Portable X-ray Unit is as safe and effective as the predicate device, has the same indications for use, has few technological differences, which are addressed through performance testing and compliance with the standards listed above, thus rendering it substantially equivalent to the predicate device.