August 13, 2021

NEUF Inc.
% Woo Sung Park
Consultant
MEDMONTS Co., Ltd.
Life-officetel 320, 40, 63-ro, Youngdeungpo-gu
Seoul, 07345
REPUBLIC OF KOREA

Re: K211383
Trade/Device Name: NFLK-2501 Portable X-ray Unit
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: April 26, 2021
Received: May 17, 2021

Dear Woo Sung Park:

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,

Laurel M. Burk -S

Digitally signed by Laurel M. Burk -S
Date: 2021.08.13 10:00:20 -04'00'

, 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)*
K211383

Device Name
NFLK-2501 Portable X-ray Unit

Indications for Use *(Describe)*
The NFLK-2501 Portable X-ray Unit is a portable X-ray device, intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).
The device may be used for handheld diagnostic imaging of body extremities.
The system is subject to the following limitations of use when stand-mounted:
- The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities.
- The device may be used for imaging of the chest when used without a grid.
This device is not intended 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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005_510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: **K211383**

I. SUBMITTER

NEUF Inc.

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Person: Eun Ho Jung

Position: RA/QA

Date Prepared: Apr.24, 2021

II. DEVICE

Name of Device: NFLK-2501 Portable X-ray Unit

Regulation Name: Mobile X-ray System

Regulation Number: 21 CFR 892.1720

Regulatory Class: Class II

Product Code: IZL

III. PREDICATE DEVICE

Manufacturer: MinXray, Inc.

Name of Device: MinXray, Model HF120/60H PowerPlus

510(k) number: K040046

Regulation Name: Mobile X-ray System

Regulation Number: 21 CFR 892.1720

Regulatory Class: Class II

Product Code: IZL

IV. DEVICE DESCRIPTION

The NFLK-2501 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 NFLK-2501. In addition, this unit has preset memory keys to store and select kV, The NFLK-2501 is used with a flat-panel detector.

This device is a mains-powered Mobile X-ray System, 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 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 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.

This 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. The NFLK-2501 is designed for handheld or stand-mounted imaging. The NFLK-2501 can be configured to an optional portable stand/rack (see optional stands in 4.2) 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.

The cybersecurity risks of the NFLK-2501 have been addressed to assure that no new or increased cybersecurity risks were introduced as a part of device risk analysis. These risks are defined as sequence of events leading to a hazardous situation, and the controls for these risks were treated and implemented as proposed in the risk analysis (e.g., requirements, verification).

V. INDICATIONS FOR USE

The NFLK-2501 Portable X-ray Unit is a portable X-ray device, intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities).

The device may be used for handheld diagnostic imaging of body extremities.

The system is subject to the following limitations of use when stand-mounted:

- The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities.

- The device may be used for imaging of the chest when used without a grid.

This device is not intended for mammography.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison between the overall specifications of predicate device (MinXray HF120/60HPowerPlus™) and the subject device (NFLK-2501 mobile X-ray system) is shown in Table 1.

Table 1 Comparison of Technology Characteristics

Item	**Predicate Device** MinXray HF120/60HPowerPlus™ (K040046)	**Subject Device** NFLK-2501 (without digital imaging)
Indications for use	This radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammographic use.	The NFLK-2501 Mobile X-ray System is intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). The system may be used for handheld diagnostic imaging of body extremities. The system is subject to the following limitations of use when stand-mounted: - The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities. - The device may be used for imaging of the chest when used without a grid. This system is not intended for mammography.
Weight	17.94 kg	11.5 kg
Size	453*292*224 mm	365 * 190 * 185 mm
Output	60 mA(0.01-0.1sec), 42 mA (0.11 – 5.0sec) @ 40 - 50 kVDC 50 mA(0.01-0.1sec), 35 mA (0.11 – 5.0sec) @ 52 - 60 kVDC 45 mA(0.01-0.1sec), 31.5 mA (0.11 – 5.0sec) @ 62 - 70 kVDC 38 mA(0.01-0.1sec), 26.6 mA (0.11 – 5.0sec) @ 72 - 80 kVDC 33 mA(0.01-0.1sec), 23.1 mA (0.11 – 5.0sec) @ 82 - 90 kVDC 30 mA(0.01-0.1sec), 21 mA (0.11 – 5.0sec) @ 92 - 100 kVDC 20 mA(0.01-0.1sec), 14 mA (0.11 – 5.0sec) @ 102 - 120 kVDC	40~50kV/51~60kV/61~70kV/71~80kV: 30mA 61~70kV: 35mA 71~80kV/81~90kV/91~100kV: 25mA 81~90KV/91~100kV: 20mA

Use Interface	Up-Down pushbuttons for kVp selections and exposure time selections with LED indicators mAs indicator	Pushbuttons with LED indicators
Exposure time	(0.01– 0.2sec) in 0.01sec. Step (0.2-0.4sec) in 0.02sec. Step (0.4-1.0sec) in 0.05sec Step (1.0-5.0sec) in 0.1sec Step	(0.01~4.0, 0.01~1.8, 2.7~3.3, 0.01~1.7, 2.5~3.2, 0.01~1.6, 2.5~4.0, 0.01~1.3, 2.0~4.0) sec
Memory Settings (technique)	5 memories	8 memories
HF Generator	85 kHz	50 kHz
kW	2.4 kW peak	2.5 kW
kVp	40-120 kVp	40-100 kVp
X-ray Tube	Superior X-ray Tube Company SXR-130 1.2 mm, 65 kHU	D-125 CANON(TOSHIBA) & OX/125-1.2(CEI) 1.2mm, 35kHU
Collimator	Advantech	DGI
Flat-panel detector	None	Either RAYENCE 1717/SGC declared in K171419 or 1717/SCC declared in K171420 VIEWORKS VIVIX-S 1717V declared in K181003
Flat-panel detector specifications	None	1717/SGC: 127u 3,328 x 3,328 pixels 1717/SCC: 127u 3,328 x 3,328 pixels VIVIX-S 1717V: 140u 3072 x 3072 pixels

Photo		

VII. Non-clinical testing:

Testing was performed successfully according to the following standards:

IEC 60601-1:2005/AMD1: 2012 EN 60601-1:2006/A1:2013	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 / EN60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-3:2008/ A11:2016	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008)
IEC 60601-2-54:2015/ EN 60601-2-54:2015	Medical electrical equipment -- Part 2-54: Particular requirements for the basic safety and essential performance of X ray equipment for radiography and radioscopy

Furthermore, the following Specific Guidance Document was utilized in the device development to ensure the safety of this device for both the operators and patients:

- "The Content of Premarket Submissions for Software Contained in Medical Devices"
- "Guidance for the Submission of 510(k) for Solid State X-ray Imaging devices"
- Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017.
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 2005
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices issued on October 2018

All applicable aspects of these guidance documents listed in this 510(k) summary have been addressed. The device also conforms to the following:

- 21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products
- 21 CFR 1020.30: Diagnostic x-ray system and their major components

VIII. CONCLUSIONS

After analyzing bench tests, it is the conclusion of NEUF Inc. that the NFLK-2501 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.