July 10, 2022

HDT Co., Ltd.
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St., Suite 610
HOUSTON TX 77054

Re: K213405
Trade/Device Name: MINE ALNU
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: May 13, 2022
Received: May 13, 2022

Dear Mr. Kim:

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 Burk, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213405

Device Name
MINE ALNU

Indications for Use *(Describe)*
Mine 2.1 is a portable medical diagnostic-purpose X-ray generator that can be hand-held. The device uses an adjustable tube voltage and a fixed tube current for producing diagnostic x-ray images of extremities for both adults and pediatrics. It is intended to be used by a qualified and trained clinician on all patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) 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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Traditional 510(k) SUMMARY

K213405

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

1. Date 510K summary prepared : 5/9/2022

2. Contact Information:

Submitter's Name :	HDT Co, Ltd.
Submitter's Address:	# 202-ho, 29, Uchi-ro 880beon-gil, Buk-gu, Gwangju, Republic of Korea, 61042
Submitter's Telephone:	+82-624537752
Contact person:	Ms. Anna Kwon/ Planning Team Manager
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Official Correspondent:	Dave Kim (davekim@mtech-inc.net)
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Telephone:	+713-467-2607

3. Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Trade/proprietary name:	MINE ALNU
Model:	Mine2.1
Regulation Name:	Mobile X-ray System
Regulation Number:	21 CFR 892.1720
Regulatory Class:	II
Product Code:	IZL

Predicate Device	
Manufacturer:	Remidi Co., Ltd
Device:	Remex KA6
510(k) Number:	K212144
Regulation Name:	Mobile X-ray System
Regulation Number:	21 CFR 892.1720
Regulatory Class:	II
Product Code:	IZL

4. Device Description

Mine 2.1, a portable X-ray generator, is radiation medical equipment that can only be used by professional radiologists. It controls and marks X-ray dose within the range of X-ray exposure limited by hardware. Also, it uses the algorithm of X-ray output for processing and control. This portable X-ray generator requires equipment for X-ray imaging in order to generate X-ray images. Small in size, this product is convenient to carry with, and suitable for being moved around. The main body can be compatibly used with a stand. When attached to a stand, it is easy to adjust positioning for medical imaging. MINE ALNU is programmed to be inoperable when the SSD is less than 40cm to the irradiation target.

The VL53L1X, a laser-ranging sensor, the fastest miniature Time-of-Flight (ToF) sensor on the market with accurate ranging up to 4 m and fast ranging frequency up to 50Hz. VL53L1X contains a laser emitter and corresponding drive circuitry. The laser output is designed to remain within Class 1 laser safety limits under all reasonably foreseeable conditions including single faults in compliance with IEC 60825-1: 2014.

The x-ray detectors, a necessary part of a complete imaging system, are not part of the current submission. The device is not intended to be used with a mechanical grid.

5. Indications for Use

Mine 2.1 is a portable medical diagnostic-purpose X-ray generator that can be hand-held. The device uses an adjustable tube voltage and a fixed tube current for producing diagnostic x-ray images of extremities for both adults and pediatrics. It is intended to be used by a qualified and trained clinician on all patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for different exam types.

6. Summary of Design Control Risk management

Mine 2.1 portable X-ray series have been developed to provide the mobility of X-ray users for convenient access to patients while meeting the critical functional requirements and international safety standards. The risks and the hazardous impact of the device design were analyzed with FMEA method. The specific risk control and protective measures to mitigate the risks from the device design and production phase were reviewed and implemented in the new product design phase. The overall assessment concluded that all risks and hazardous conditions identified arising from the design and production were successfully mitigated and accepted.

7. Summary of the technological characteristics of the device compared to the predicate device:

Mine 2.1 portable X-ray series described in this 510(k) have the similar indications for use and technical characteristics as the predicate device, Remex KA6 (K212144) manufactured by Remedi Co., Ltd.

8. Substantial Equivalence

Mine 2.1 mobile X-ray system conforms to the FDA recognized standards as like the predicate device. Based on the recognized standard conformity evidences related to

electro-, mechanical-, software-, clinical-, and risk management, it is confirmed that Mine 2.1 diagnostic X-ray system is substantially equivalent to the predicate device.

Device	Mine ALNU (Model: Mine 2.1) Mobile X-ray System	Remex KA6 (K212144)	
Manufacturer	HDT Co., Ltd	Remedi Co., Ltd	
Indications for use	Mine 2.1 is a portable medical diagnostic-purpose X-ray generator that can be hand-held. The device uses an adjustable tube voltage and a fixed tube current for producing diagnostic x-ray images of extremities for both adults and pediatrics. It is intended to be used by a qualified and trained clinician on all patients. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for different exam types.	The KA6 is a portable X-ray system for diagnostic imaging of body extremities.	Similar
Energy Source	Li-ion rechargeable battery (21.6 Vdc, 2,500 mAh)	Lithium polymer rechargeable battery (DC 22.2 V, 1,800 mAh)	#1
User Interface	40 ~ 80 kV (1 kV step) Up and down Rotary switch	40 ~ 70 kV (1 kV step) Up-Down pushbuttons for selection of exposure time, kVp, and mA, with LED indicators	Similar
Exposure switch	Dual stage, deadman type	Dual stage, deadman type	Same

Controls	Software based	Software based	Same
Construction	Monobloc HF generator, Medical full bridge inverter system	Monobloc HF generator, Medical full bridge inverter system	Same
High Voltage Adjustment	High frequency inverter	High frequency inverter	Same
Line Voltage Adjustment	Automatic, Dynamic	Automatic, Dynamic	Same
Exposure times (sec)	0.1 – 1.3 sec, 0.1 sec step	0.06 – 2.0 sec (0.01 sec. steps)	Similar
Tube Potential (kV)	40 ~ 80 kV (1 kV step)	40 ~ 70kV (1 kV step)	Similar
Tube current	3 mA (Fixed)	2~ 6mA (1 mA step)	#2
X-ray tube	Haewoo H-80	Canon D-041SB (Heat anode 4300J)	#3
Focal Spot	0.4 mm	0.4mm	Same
Total Filtration	1.0 mmAl	1.6 mm Al	#4
Collimator	Square collimator with LED Light Field Center Indicator	Square collimator with LED Light Field Center Indicator	Same
Performance Standard	21CFR 1020.30	21CFR 1020.30	same
Electrical Safety	IEC 60601-1: 2005 (3rd) + A1: 20121 IEC 60601-1-3: 2013 IEC 60601-2-28: 2017 IEC 60601-1-2: 2014 IEC 60601-2-54: 2009	IEC 60601-1: 2012 IEC 60601-1-3 : 2013 IEC 60601-2-28: 2017 IEC 60601-1-2: 2014 IEC 60601-2-54 : 2009	same
X-ray Radiography	Conventional X-ray film or digital imaging detector	Conventional X-ray film or digital imaging detector	same

9. Discussion of Differences

SE-#	SE discussion
1, 2	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 3mA whereas the predicate device can vary between 2mA ~ 6mA. Both exposure power settings are capable of producing diagnostic x-ray images of extremities for adult and pediatric patients.
3	X-ray tube specifications are different but both X-ray tube models are capable of producing diagnostic x-ray images of extremities for adult and pediatric patients.
4	The minimum filtration reduces patient radiation dose by eliminating low energy that would otherwise be absorbed by the patient's skin. Positive means are determined through linear interpolation to provide that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure, according to the HVL provisions of 1020.30(m)(1).

10. Summary of the technological characteristics of the device compared to the predicate device:

The indications for use, mechanical components, performances and safety characteristics of Mine 2.1 portable X-ray series described in this 510(k) are similar to those of the predicate device.

The primary differences are the specifications of X-ray tube, and X-ray generator of the subject device. The performance specifications of the subject device are similar or higher than that of the predicate device such as the X-ray generator and X-ray tube

anode heat content (Heating Unit).
These differences do not have any effects on safety and effectiveness compared to the predicate device.

11. Performance Testing/Data

Testing for verification and validation of the device was found acceptable to support the claims of substantial equivalence. Safety and EMC compliance were evaluated according to the IEC Standards. *Radiation leakage test and image quality studies have been tested and the results met the acceptance criteria and limitations of the subject device.* HDT Co., Ltd certifies conformance to Voluntary Standards covering electrical and mechanical safety. In conclusion, the identified risk of electrical hazards was mitigated and is substantially equivalent to the predicate device in terms of safety and effectiveness.

12. Description of non-clinical tests.

Mine 2.1 diagnostic X-ray system has been tested for electrical safety and electromagnetic compatibility (IEC 60601-1-2, IEC , IEC 60601-2-54, IEC 60601-1-3, IEC 60601-2-28, and IEC 60601-1:2005.) The device also complies with FDA EPRC Performance Standard: 21 CFR 1020.30 and 31. The software validation and verification testing was also performed. The results of nonclinical testing indicate that the Mine 2.1 mobile X-ray system is as safe and effective as the predicate device.
Compliance evidences were submitted for the following standards:

- IEC 60601-1: Test Report issued by 3rd party testing lab
- IEC 60601-1-2: Test Report issued by 3rd party testing lab
- IEC 60601-1-3: Test Report issued by 3rd party testing lab
- IEC 60601-2-54: Test Report issued by 3rd party testing lab
- EPRC Standard: 21 CFR 1020.30 and 31: In-house Test Report

- ISO 14971: Risk management file

13. Description of clinical tests.

No clinical data is necessary to evaluate safety or effectiveness for purposes of determining substantial equivalence of the proposed modification. Bench testing was performed to assess the device safety and effectiveness.

14. Conclusion as to Substantial Equivalence

MINE 2.1 are substantially equivalent to the predicate device P Remex KA6 (K212144). These 2 devices are very similar in the intended use, the design principle, the performance and the applicable standards. Some characteristics, for example, their appearance, the user interfaces and the capacity of X-ray generator and X-ray tube are different. However the compliance reports, performance demonstrations and description of non-clinical review result in this submission STED provide demonstration that these differences do not raise any new questions of safety and effectiveness. Therefore, HDT CO., LTD. concludes Mine 2.1 of mobile X-ray system are substantially equivalent with the predicate device Remex KA6 (K212144) of Remedi Co., Ltd.