RHT Co., Ltd.
% Ms. April Lee
Consultant
Withus Group, Inc.
106 Superior
IRVINE CA 92620

June 5, 2019

Re: K180671
Trade/Device Name: MINE
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: May 16, 2019
Received: May 17, 2019

Dear Ms. 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180671

Device Name
MINE

Indications for Use *(Describe)*
The MINE is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.

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

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Device Information

- K number: K180671
- Trade Name: MINE
- Common Name: Portable X-ray System
- Classification Name: Extra-oral source x-ray system
- Product Code: EHD
- Panel: Dental
- Regulation Number: 872.1800
- Device Class: Class II
- Date prepared: 06/04/2019

Predicate Device

- K number: K122124
- Trade Name: EXARO
- Common Name: Portable X-ray System
- Classification Name: Extra-oral source x-ray system
- Product Code: EHD
- Panel: Dental
- Regulation Number: 872.1800
- Device Class: Class II

Device Description

MINE, a portable dental X-ray system, operates on 11.1V DC supplied by a rechargeable LiPolymer battery pack, The X-ray tube head, controls and power source are assembled into a single hand-held enclosure. The package includes a battery charger.
The portable X-ray system, MINE, being composed of X-ray generator, controller, and beam limiting device is designed to diagnose tooth and jaw through generated and controlled X-ray. The operating principle of MINE starts from the generation of X-ray by high voltage electricity, which in turn penetrates tooth and jaw area after flowing through X-ray tube and produces X-ray images on X-ray receptors (i.e. chemical film or digital sensor)
This device contains a high frequency inverter that converts direct to alternating current, X-ray tube head, electrical protective devices, and other elements. The MINE produces sharp and clear images and prevents patients and dentists from radiation exposure with utilizing small dose of radiation.

Characteristic		MINE
Anode current		2mA
Expose time		0.01~1.3sec
Battery	Battery part No.	BT17070001
	Battery Current	1500mA
	Battery Max. Current	25A
Battery case size		(max) 52x62x22

Indications for use

The MINE is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.

Summary of Technological Characteristics

	NEW	**Predicate Device**
Manufacturer	RHT Co., Ltd.	OSSTEM IMPLANT Co,. Ltd.
Model	MINE	EXARO
510(k) Number	K180671	K122124
Energy Source	Rechargeable 11.1V, DC Lithium Polymer Battery pack	Rechargeable 25.2V, DC Lithium Polymer Battery pack
Expose Time	0.01sec ~ 1.30sec	0.01~2.0 seconds, 0.01 increments
Time Accuracy	±(10%+1ms)	±(10%+1ms)
Heat Capacity	4300J (6 KHU)	8.5 KHU
Power Output	100W	100W
mA	2mA Fixed	2mA Fixed
kVp	60kV Fixed	60kV Fixed
Focal Spot	0.4mm	0.8mm
Wave Form	Constant Potential (DC)	Constant Potential (DC)
Safety, EMC and Performance	IEC/EN 60601-1, IEC/ EN 60601-1-3 and IEC/EN 60601-2-28	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28
Source to skin Distance	20cm	20cm
Cone Diameter	6cm	6cm
User Interface	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor with	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor

	display. 12channel save.	with display.
Exposure switch	Control panel key	Control panel and remote controller
Tube head Mounting	Yes	Yes
Principle of Operation	X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor)	X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor)
Intended Use	intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.	

The subject and predicate devices are similar in indications, design, technology, functions, source to skin distance and principle of operation.
The difference between the two devices is as follows.

- Heat Capacity: The heat capacity of the subject device is 4300J and predicate device's is 6000J. The subject device has Less Heat Capacity than the predicate device, but the efficiency is similar.
- Focal Spot: The focal spot of the subject device is 0.4mm and predicate device's is 0.8mm. Reducing focal spot size results in a sharper image quality than predicate device.
- Energy Source: The Energy source of the subject device is 11.1V and predicate device's is 25.2V. Since this product is designed with low voltage, it can be used with low voltage battery.

Any differences do not raise different questions of safety and effectiveness than the predicate. Therefore, there is no difference between the subject and predicate with respect to the indications or technology.

Non-clinical Testing

The compliance of MINE will satisfy the applicable requirements of the Underwriters Laboratories Standard for Safety-IEC/EN 60601-1, IEC/ EN 60601-1-3, IEC/EN 60601-2-28 and IEC 60601-2-65. All required documents and reports will be submitted to the appropriate oversight agency to establish compliance with the applicable requirements.
EMS test was performed for MINE in accordance with Standard EN/IEC 60601-1-2. All test results were complied with the requirements.
Phantom images were provided to demonstrate the overall performance of the device as part of a complete intraoral x-ray imaging chain.
The subject device, MINE was found to be compliant with all applicable federal performance standards under 21 CFR 1020.

Conclusion

In reference to the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807 and the comparison information provided substantial equivalent chart above, the RHT Co.,Ltd. believes that the MINE is substantially equivalent to its predicate device.