April 22, 2022

Digimed Co., LTD.
℅ Youngbae Kwon
CEO
145, Gasan digital 1-ro, Geumcheon-gu
Seoul, SEOUL 08506
SOUTH KOREA

Re: K220574
Trade/Device Name: HYBRID S70
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: February 28, 2022
Received: February 28, 2022

Dear Youngbae Kwon:

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
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)*
K220574

Device Name
HYBRID S70

Indications for Use *(Describe)*
HYBRID S70 is intended to be used by trained dentists and dental technicians as a portable and a mobile, extra-oral X-ray source. This can help producing diagnostic x-ray images by using with various intra-oral image detectors. This x-ray image can be used for dental examination (diagnosis) before or after treatment. 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

(Submission number: **K220574**)

1. Company and Correspondent Making the Submission

Date prepared	February 22, 2022
Company name	DIGIMED Co., Ltd.
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E-mail	digimed@digimed.co.kr
Contact	Mr. Joonghyun Choi, RA Team manager

2. Device Information

Trade name	**HYBRID S70**
Common name	Portable X-Ray System
Regulation name	Extra-oral source x-ray system (21CFR 872.1800)
Device Class	Class II
Product Code	EHD

3. Predicate Device

510(k) Owner	Metabiomed, Inc.
Trade name of device	Rextar X
Common Name	Portable X-Ray System
Regulation name	Extra-oral source x-ray system (21CFR 872.1800)
510(k) Number:	K132041
Device Class	Class II
Product Code	EHD

4. Description of Device

The portable x-ray system **HYBRID S70**, is an x-ray generating device which is designed for dental examination.

The device has an x-ray tube for generating x-ray, a high voltage transformer for generating high voltage, a high voltage rectification circuit for transforming and boosting AC voltage to mixed pulse voltage, a high voltage divide circuit for lowering high voltage to low voltage to measure and calibrate high voltages, as well as a high voltage tube tank, a high frequency inverter circuit for generating high voltages, a control P.C.B for controlling, an LCD display for saving and displaying the x-ray exposure setting, a power P.C.B with super capacitors for

supplying power to the circuit and apparatus in housing, and beam limiting part (x-ray emitting cone).
The apparatuses above can be embedded in one or several cases, and except for the radiation opening in the x-ray system, all units are completely shielded by lead or high-density materials, protecting patient and operator from unnecessary exposure of radiation.
The package includes a remote control switch, a battery charger, and a backscatter shield. And the remote control switch can be used when the device is mounted on optional stands or digital camera tripods.
Operating principle of the device starts from the generation of the high voltage electricity. Once the x-ray exposure button is pressed, the battery power supplied super capacitors on Power P.C.B delivers the electricity to the high voltage transformer. And the 70kV of high voltage generated from the transformer goes into the x-ray tube and makes x-ray source. And this x-ray source is exposed through the emitting cone. When the x-ray source is exposed to patient's teeth, the x-ray image detectors behind the teeth capture and make x-ray images.
(**The image detectors are not part of this submission.**)
Since the device can generate high frequency x-ray with the transformed and boosted AC voltage through high voltage generator, operator is able to obtain more improved and visible x-ray image of patient.

Main features;

- High frequency x-ray generator: 70 kV & 2 mA fixed
- X-ray tube focal spot: 0.4 mm
- Source to skin distance (SSD): 20 cm fixed
- Half value layer (HVL): Over 1.5 mmAl
- Ergonomic design: Pistol grip with a x-ray exposure trigger
- Rechargeable battery: 14.8V
- Compatible with most of the x-ray image detectors
- Compact size: 120 x 245 x 225 mm
- Light weight: 2.0 kg

5. Intended Use (Indications for Use)
HYBRID S70 is intended to be used by trained dentists and dental technicians as a portable and a mobile, extra-oral x-ray source. This can help producing diagnostic x-ray images by using with various intra-oral image detectors. This x-ray image can be used for dental examination (diagnosis) before or after treatment. Its use is intended for both adult and pediatric subjects.

Compatible intra-oral image detectors are listed below.

1) Analog dental x-ray films
2) CCD and CMOS digital sensors (IO sensor)
3) Digital phosphor plates (PSP)

*If any image detectors are developed for x-ray detection, they must react with the x-ray from this device.

6. Technological Characteristics compared to the predicate device

Device name	**HYBRID S70**	**Rextar X**
Intended Use/ Indications	The device is intended to be used by trained dentists, dental assistants, hygienists, and radiologists. The device can produce diagnostic x-ray images by using with various intra-oral image detectors. This x-ray image can be used for dental examination (diagnosis) before or after treatment. Dental caries, cavity, crack, or other conditions can be detected by the examination. Its use is intended for both adult and pediatric subjects.	To be used by trained dentists and dental technicians as a mobile, extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. It is intended for both adult and pediatric subjects. X-ray system design to provide images of the patients undergoing dental procedures. Clinical uses include Bite wing, periapical, occlusal and panoramic images.
User interface display	LCD panel display (2.6 inch, FSTN LCD, 1/4 duty 1/3 BIAS)	LCD panel display (3.5 inch, BTN LCD, 1/4 duty 1/3 BIAS)
Exposure switch	Exposure button at front cover on right hand side, or a remote control switch	Exposure button at front cover on right hand side
Source to skin distance	200 mm	200 mm
Cone diameter	53 mm	55 mm
Half-value layer	Over 1.5 mmAl	Not identified
Exposure time	0.05~1.0 seconds in 0.01 increments	0.01~1.3 seconds (43 steps)
Time Accuracy	± (10% +1 ms)	± (10% +1 ms)
kVp	70 kV fixed	70kV fixed
mA	2 mA fixed	2 mA fixed
Focal spot	0.4 mm	0.4 mm
Tube type	Stationary	Stationary
Waveform	High Frequency DC	High Frequency DC
Energy source	Rechargeable 14.8 V DC Lithium Polymer battery pack	Rechargeable 11.1 V DC
Dimension	120(w) x 245(d) x 225(h) mm	146(w) x 239(d) x 155(h) mm
Weight	2.0 kg	2 kg
EMI standards	EN60601-1-2, IEC60601-1-2 CISPR 11, IEC61000-3-2 IEC61000-3-3	EN60601-1-2, IEC60601-1-2
Performance standards	IEC 60601-1 IEC 60601-1-3 IEC 60601-1-6 IEC 60601-2-65 IEC 62304	IEC 60601-1 IEC 60601-2-7 IEC 60601-2-28 IEC 60601-2-32

7. Safety and Effectiveness, Comparison to Predicate Device

Safety and effectiveness of the subject device is considered with the latest version of test regulations. The subject device was shown to provide an equivalent level of safety and performance as compared to the predicate devices.

"Clinical images were provided however they were not necessary in order to establish substantial equivalence with the predicate devices"

8. Safety, EMC and Performance Data:

The subject device complies with the safety and performance standards listed in the chart above. Test reports were provided to demonstrate conformance. All required documents and reports are submitted to the appropriate oversight agency to establish compliance with the applicable requirements.

9. The differences between the subject device and the predicate devices

The subject device has little differences with its design, size, and user interface compare to the predicate devices. Detailed differences can be identified from "Substantial Equivalence Chart".

12. Conclusion

As stated above, the Portable x-ray system **HYBRID S70** is safe and effective and complies with the appropriate medical device standards and is substantially equivalent to the earlier identified predicate devices.