April 4, 2022

Energy Resources International Co., Ltd. Hsinchu Branch
℅ Ms. Judy Chiang
QA&RA Specialist
2F-2, No. 6-1, Sec. 2, Zhengyi Rd
Zhubei City, Hsinchu County 30261
TAIWAN

Re: K213282
Trade/Device Name: ERI Handheld Dental X-ray System (Model AG100)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD, MUH
Dated: September 27, 2021
Received: October 1, 2021

Dear Ms. Chiang:

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)*
K213282

Device Name
ERI Handheld Dental X-Ray System (Model AG100)

Indications for Use *(Describe)*
ERI Handheld Dental X-Ray System (Model AG100) is intended for the purpose of using it for both adult and pediatric patients by qualified operators (e.g. dentist and/ or radiographer, etc.) regulated by competent authority of each country for producing diagnostic dental X-ray images.

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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ENERGY RESOURCES INTERNATIONAL CO., LTD.

510(k) Submission

AG100

Section 5

510(k) Summary

The assigned 510(K) number: K213282
Date Prepared: 09/27/2021

I. Submitter Information

Submitter:
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II. Subject Device

Trade Name: ERI Handheld Dental X-Ray System (Model AG100)
Regulation Name and Classification:

No.	Product Code	Regulation Name	Regulatory Class	Regulation Number	Panel
1	EHD	Extraoral Source X-Ray System	II	872.1800	Radiology
2	MUH	Extraoral Source X-Ray System	II	872.1800	Radiology

III. Predicate Device

510(K) Number	K173319
Manufacturer	Aribex
Device Name	KaVo NOMAD Pro 2 Handheld X-Ray System
Regulation Name	Extraoral Source X-Ray System
Regulation Number	872.1800
Product Code	EHD
Regulatory Class	II

IV. Device Description

It can be used with computed radiography (CR) detection film, digital radiography (DR) detection film or traditional film (dental film) to take intraoral X-rays and provide the information needed by the dentist for diagnosis.

As a preoperative, intraoperative, and postoperative evaluation for identifying dental caries or auxiliary root canal treatment, as well as confirming the position of the implant during dental implant surgery. It can take pictures of the apex of the front and back teeth, as well as the bite of

the back teeth. Applicable objects include adults and children.

Due to the medical software included in radiation-emitting device, ERI handheld system is of Moderate level of concern.

The AG100 device, as well as, the predicate device (Trade Name: KaVo NOMAD Pro 2 Handheld X-Ray System manufactured by Aribex (K173319)) utilize a fixed tube current and voltage (kVp) to achieve their intended use.

V. Indications for Use

ERI Handheld Dental X-Ray System (Model AG100) is intended for the purpose of using it for both adult and pediatric patients by qualified operators (e.g. dentist and/ or radiographer, etc.) regulated by competent authority of each country for producing diagnostic dental X-ray images.

VI. Comparison of Technology Characteristics with the Predicate Device

Energy Resources International claims that the AG100 device is substantially equivalent to the KaVo NOMAD Pro 2 Handheld X-Ray System cleared by the FDA in K173319. Energy Resources International claims substantial equivalence because the AG100 has an equivalent intended use, operating principles, and operational specifications as compared to the predicate device.

The specific details regarding the similarities and differences between the AG100 and KaVo NOMAD Pro 2 Handheld X-Ray System have been identified and explained in the Comparison Table, see the following table 3. A summary of these similarities and differences is included below. These differences do not present any new issues related to safety and effectiveness.

Device name	**Kavo NOMAD Pro 2 Handheld X-ray system (Predicate Device: K173319)**	**ERI Handheld Dental X-Ray System (Model AG100)**
Classification, regulation number, product code	Extraoral Source X-ray System, 21 CFR 872.1800, EHD	Extraoral Source X-ray System, 21 CFR 872.1800, EHD/ MUH
Intended Use	The KaVo NOMAD Pro 2 Handheld X-ray System is indicated for use only by a trained and qualified dentist or dental technician for both adult and pediatric subjects as an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors.	ERI Handheld Dental X-Ray System (Model AG100) is intended for the purpose of using it for both adult and pediatric patients by qualified operators (e.g. dentist and/ or radiographer, etc.) regulated by competent authority of each country for producing diagnostic dental X-ray images.
Mechanical		

Source to skin distance	20 cm	20 cm
Cone diameter	6 cm	6 cm
Backscatter radiation protection	6.75" dia. Pb-filled acrylic plastic scatter shield	153mm(6.02") dia. Pb-filled acrylic plastic scatter shield
Exposure switch	Trigger located on handset	Trigger located on front top
Electrical		
Energy Source	Rechargeable 21.6 V DC Li-ion battery core pack	Rechargeable 14.4 V DC Li-polymer battery core pack
Capacity	1.7 A-hr	2.4 A-hr (34.56Wh)
Casing	Hard shell case	Hard shell case
Recharge capability	70% remaining capacity after 300 cycles	After 300 cycles, more than 70%
Exposure Time	0.02 – 1.0 seconds in 0.01 increments	0.1 – 2.0 seconds in 0.01 increments
mA	2.5 mA fixed	0.6 mA fixed
kVp	60 kVp fixed	60 kVp fixed
Duty Cycle	1:60	maximum 60 sec after previous shot
Electrical Safety Standards	AAMI ES60601-1:2005/(R)2012 And A1:2012	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
EMI Standards	IEC60601-1-2 Ed. 4	IEC60601-1-2:2014 Ed. 4
X-ray Performance		
Performance Standard	21 CFR 1020.30, 1020.31; IEC60601-1-3; IEC60601-2-65	21 CFR 1020.30, 1020.31; IEC 60601-1-3 Edition 2.1; IEC 60601-2-65 Edition 1.1 CONSOLIDATED VERSION; IEC 61223-3-4 First edition

Hence, the subject device is similar to the predicate device in terms of the indications for use and technological application.

VII. Non-clinical Test Data

Testing was performed in accordance with the following international standards:

- IEC 62304 Edition 1.1 [2015-06] Medical device software - Software life cycle processes
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0 [2014-02] Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-3 Edition 2.1 [2013-04] Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-65 Edition 1.1 [2017-05] Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment
- IEC 61223-3-4 First edition [2000-03] Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray
- ISO14971 Third Edition [2019-12] Medical devices - Applications of risk management to medical devices
- ISO10993-2 Second edition [2006-07-15] Biological Evaluation of medical devices - Part 2: Animal welfare requirements
- ISO10993-5 Third edition [2009-06-01] Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO10993-10 Third Edition [2010-08-01] Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO10993-12 Fourth edition [2012-07-01] Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- 21 CFR 1020.30: Diagnostic x-ray system and their major components
- 21 CFR 1020.31: Radiographic Equipment

VIII. Clinical Performance Data

The function and performance of the AG100 have been evaluated through non-clinical design verification and validation tests. Testing included electrical performance evaluations and usability test. The results of the AG100 performance evaluations demonstrate that the device design is well suited for its intended use. Clinical testing has not been conducted on this product, and successful bench testing results should be sufficient in demonstrating substantial equivalence for the AG100 handheld system.

IX. Conclusions

The Energy Resources International AG100 has the same intended use and same basic technology as the predicate device, thus is able to achieve the same effectiveness and safety as the predicate device. The AG100 contains in some combination similar features and design as the predicates. Other differences include device design such as exposure time, size and user interface. The subject device is substantially equivalent to the predicate device with its intended use, mechanical and electrical performance as described.