June 27, 2022

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

Re: K221233
Trade/Device Name: DT-703
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: April 20, 2022
Received: April 29, 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)*
K221233

Device Name
DT-703

Indications for Use *(Describe)*

The DT-703 is a portable dental X-ray system that captures radiographic images for dental diagnosis using intraoral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use DT-703 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

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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510(k) Summary
K221233

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

Date 510(k)submitted: 4/25/2022

1. **Submitter Information:**

Sumitter's Name:	ECOTRON Co., Ltd
Address:	404, 504, 505Ho, Hanshin IT Tower II, 47, Digital-ro 9-gil, Geumcheon-Gu, Seoul, Republic of Korea 08511
Contact Person:	Sang Bong Lee, R&D Manager
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Official Correspondent:	Dave Kim, MBA Mtech Group
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Tel:	713-467-2607
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2. **Device Name:**

Proprietary Name:	DT-703
Manufacturer Name:	ECOTRON
Common Name:	Handheld X-ray System
Classification Name:	Extraoral Source X-ray System
CFR Number:	872.1800
Device Class:	II
Product Code:	EHD

3. **Predicate Device:**

Proprietary Name:	KaVo NOMAD Pro 2 Handheld X-ray System (K173319)
Manufacturer Name:	Aribex
Common Name:	Handheld X-ray System
Classification Name:	Extraoral Source X-ray System
CFR Number:	872.1800
Device Class:	II
Product Code:	EHD

4. Description of Device:

DT-703 is a handheld X-ray system powered by a rechargeable Li-ion polymer battery pack. DT-703 is an extra source X-ray generating device that is mainly designed for dental examination (on teeth, etc.). DT-703 is composed of X-ray generator with X-ray tube including device controller, power controller, user interface, beam limiting part, backscatter shielding glass, and optional remote exposure switch. DT-703 is designed to diagnose teeth and jaw through X-ray irradiation using an intra-oral image receptor. DT-703 is controlled by software (firmware) and the software level of concern is Moderate. The x-ray image detector (an integral part of a complete dental diagnostic system) is not part of the DT-703 X-ray device.

Optional parts available:

- Remote Exposure Switch
- Backscatter Shield
- Rectangular Cover (FOV 2x3)
- Rectangular Cover (FOV 3x4)

5. Indications for Use:

DT-703 is a portable dental X-ray system that captures radiographic images for dental diagnosis using intraoral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use DT-703 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.

6. Description of Substantial Equivalence: Technological Characteristics:

DT-703 has similar design components and operating features as the predicate device, KaVo NOMAD Pro 2 Handheld X-ray System (K173319).

The handheld device features a main unit (tube head), rechargeable battery (handset) and charger. The main components of the tube head including X-ray tube (70 kV, 3 mA), internal shielding and external backscatter shielding are similar to the predicate device. The functionality of the user interface is also similar to the predicate device.

The power is supplied by a rechargeable Lithium Ion battery core pack built into a handset. The design for DT-703 is equipped with a 22.2 VDC, 1.0 Ahr battery core pack compared to the predicate device (KaVo NOMAD Pro 2 Handheld X-ray System - K173319) design of 21.6 VDC, 1.7 Ahr. The DT-703 battery core pack is compliant with IEC 62133-2.

Testing has been completed on basic safety and essential performance and the device complies with IEC 60601-1; IEC 60601-1-2 (Ed. 4.1); IEC 60601-1-3, and IEC 60601-2-65.

	DT-703 Handheld Dental X-ray System (Subject Device)	**KaVo NOMAD Pro2 Handheld X-ray System (K173319)**
INDICATIONS FOR USE:	DT-703 is a portable dental X-ray system that captures radiographic images for dental diagnosis using intraoral imaging sensors. Only trained and qualified dental practitioner or radiologist shall use DT-703 to diagnose and treat diseases related to the teeth, jaws, and/or other oral structures in adults and children.	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.
MECHANICAL:		
Size: Body (mm/inch)	259 x 277 x 165 mm (10”L x 11”H x 6.5”W)	11"L x 10.5"H x 5.5"W
Weight	1.5 kg (3.3 lbs)	6.0 lbs.
Source to skin distance	20 cm	21 cm
Cone diameter	6 cm	6 cm
User Interface	Same, plus several user-selectable preset times.	
Backscatter radiation protection	165mm (6.5”) dia. Pb-filled acrylic plastic, backscatter shield	6.75" dia. Pb-filled acrylic plastic scatter shield
Exposure switch	Trigger located on handset / optional remote switch	Trigger located on handset
Tubehead mounting	Handheld	
ELECTRICAL:		
Tubehead	CEI OX/70-3	Cyprus PSOC CY8C29866
Energy Source	Rechargeable 22.2 V Li-ion polymer battery pack	Rechargeable 21.6 V DC Li-ion battery core pack
Capacity	1.0 A-hr	1.7 A-hr
Exposure Time	0.02 – 0.5 seconds in 0.01 increments	0.02 – 1.0 seconds in 0.01 increments
mA	3 mA fixed	2.5 mA fixed
kVp	70 kVp fixed	60 kVp fixed

Electrical Safety Standards	IEC 60601-1:2005, AMD1:2012	AAMI ES60601-1:2005/(R)2012 And A1:2012
EMI Standards	IEC60601-1-2: Ed. 4.1	IEC60601-1-2 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; IEC60601-1-3; IEC60601-2-65

Similar technological characteristics for the proposed device DT-703 and the predicate device KaVo Nomad Pro2 seem to indicate substantial equivalence.

Non-Clinical Test Data:

Testing was performed in accordance with the following international standards:

IEC 60601-1:2005, AMD 1: 2012

IEC 60601-2-65 Edition 1.0 2012-09 Medical Electrical Equipment – Part 2-65: Particular Requirements for the Basic Safety And Essential Performance of Dental Intra-Oral X-Ray Equipment

IEC 60601-1-2 Edition 4.1 2014-02 Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Disturbances – 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

ISO 14971 Third Edition 3 2019 Medical Devices – Application Of Risk ManagementTo Medical Devices

IEC 62133 Edition 2.0 2012-12 Secondary Cells And Batteries Containing Alkaline Or Other Non-Acid Electrolytes – Safety Requirements For Portable Sealed Secondary Cells, And For Batteries Made From them, For Use In Portable Applications [Including: Corrigendum 1 (2013)]

FDA Guidance Documents Utilized:

Radiation Safety Considerations for X-ray Equipment Designed for Hand-Held Use, issued December 24, 2008

Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005

Pediatric Information for X-ray Imaging Device Premarket Notifications, issued May 10, 2012

Clinical Performance Data:

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

Conclusion as to Substantial Equivalence:

Based on a comparison of intended use, indications, technological characteristics, principleof operation, features and performance data, the sponsor believes that the subject device, DT-703 is deemed to be substantially equivalent to the predicate device, KaVo NOMAD Pro 2.