November 1, 2024

DRTECH Corporation
% Yeongsuk An
Official Correspondent
Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29
Dunchon-Daero 541beon-gil
Seongnam-si, 13216
SOUTH KOREA

Re: K242591

Trade/Device Name: XERO - α
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-Ray System
Regulatory Class: Class II
Product Code: EHD
Dated: August 30, 2024
Received: August 30, 2024

Dear Yeongsuk An:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242591

Device Name
Xero α

Indications for Use *(Describe)*

XERO α is an Hand-held intraoral dental x-ray equipment to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients. This equipment is used in a professional healthcare facility environment.

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

[K242591]

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

1. Date Prepared [21 CFR 807.92(a) (1)]

November/01/2024

2. Submitter's Information [21 CFR 807.92(a) (1)]

- Name of Sponsor: DRTECH Corporation
- Address: Suite No.1, 2 Floor / Suite No. 2, 3 Floor, 29, Dunchon-daero541 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13216, South Korea
- Contact Name: Yeongsuk, An
- Telephone No.: + 82-31-779-7787
- Fax No.: + 82-31-779-7790
- Email Address : drtechra@drtech.com
- Registration Number: 3005172103
- Name of Manufacturer: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a) (2)]

- Trade Name: XERO α
- Common Name: Hand-held intraoral dental x-ray equipment
- Classification Name: Extraoral source x-ray system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 872.1800
- Product Code: EHD
- Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

- 510(k) Number: K200182
- Applicant: Vatech Co., Ltd.
- Trade Name: EzRay Air Portable (Model: VEX-P300)
- Classification Name: Extraoral source x-ray system
- Classification Panel: Radiology
- Classification Regulation: 21 CFR 872.1800
- Product Code: EHD
- Device Class: II

5. Description of the Device [21 CFR 807.92(a) (4)]

XERO α is an Hand-held intraoral dental x-ray equipment to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients. This equipment is used in the professional healthcare facility environment. But the image detectors (an integral part of a complete dental system) are not part of the device.

The operation principle of the device involves emitting x-ray source when a high voltage is supplied to the X-ray tube assembly, which frees electrons from the cathode. They hit anode to produce X-rays. The device acquires images by emitting X-rays continuously on the human tooth.

And the functions of the dental generator XERO α are supported by firmware. This is of basic firmware documentation level, and there is no external data exchange port in the device. Moreover, the XERO α is not wireless. The subject dental system is not a cyber device.

6. Indication for Use [21 CFR 807.92(a)(5)]

XERO α is an Hand-held intraoral dental x-ray equipment to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients. This equipment is used in the professional healthcare facility environment.

7. Summary of Technological Characteristics of the Subject Device as Compared with the Predicate Device [21 CFR 807.92(a)(6), 21 CFR 807.92(b)]

The XERO α composed of a x-ray generator, tube, collimator and accessories.

This equipment is designed to generate and control x-ray beams. It records the absorption pattern of x-ray beams used for general-purpose, routine, dental radiography examinations involving the diagnosis and treatment (e.g., surgical or interventional) of diseases of the teeth, jaw and oral cavity structures. It is designed to be easily carried from location to location by a single operator. This equipment is used in both professional healthcare facility environment and home healthcare environment.

The Proposed device has the same fundamental scientific technologies as the predicate devices. The technological comparison table below demonstrates the comparability of the technological characteristics of the new device and the currently cleared predicate devices. The Technological differences do not affect the intended use of the device. The table 1 below compares the main performance data of the proposed device with the predicate devices to substantiate equivalence of the proposed device and predicates.

Table 1. Comparison of the Subject Device to the Predicate Device Substantial Equivalence

Parameter		Proposed Device	Predicate Device	Comparison Analysis
510(k) Number		Unknown	K200182	**N/A**
Model Name		XERO α	EzRay Air Portable (Model: VEX-P300)	**N/A**
Manufacturer		DRTECH Corporation	Vatech Co., Ltd.	**N/A**
Common Name		Hand-held intraoral dental x-ray equipment	Portable X-ray System	**Identical**
Classification Name		Extraoral source x-ray system	Extraoral source x-ray system	**Identical**
Classification Panel		Radiology	Radiology	**Identical**
Classification Regulation		21 CFR 872.1800	21 CFR 872.1800	**Identical**
Product Code		EHD	EHD	**Identical**
Device Class		Class II	Class II	**Identical**
Intended Use		XERO α is an Hand-held intraoral dental x-ray equipment to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients. This equipment is used in the professional healthcare facility environment.	EzRay Air Portable (Model: VEX-P300) is an extraoral diagnostic dental X-ray source to produce X-ray images using intraoral image receptors. It is indicated for use by a dentist or a dental technician for both adult and pediatric patients.	**Identical**
Technological characteristics - Mechanical	**Size (L x W x H)**	293 x 155 x 287 mm	280 x 165 x 296 mm	**Identical**
	Source to skin	200 mm	200 mm	**Identical**

	distance			
	X-ray field Size	60 mm round	60 mm round	**Identical**
	User Interface	Jog dial for operating mode selection. Additionally, several user selectable preset times with patient size and tooth selection icons on a display module.	Jog dial for operating mode selection. Additionally, several user-selectable preset times with patient size and tooth selection icons on a display module.	**Identical**
	Backscatter radiation protection	Back Scattering shield	165 mm dia., Pb-filled acrylic plastic, Back Scattering shield	**Identical**
	Exposure Switch	Exposure button on the handset	Exposure button on the handset	**Identical**
	Tube head mounting	Handheld	Handheld	**Identical**
Technological characteristics - Electrical	**Energy source**	Rechargeable 22.2 V DC Li-ion polymer battery pack (Nominal Capacity: 900 mAh)	Rechargeable 21.6 V DC Li-ion polymer battery pack (Nominal Capacity: 2,500 mAh)	**Identical, Justification for Identical :** Although there is a difference in battery capacity compared to the predicate device, Rechargeable 22.2 V DC Li-ion polymer battery pack has been tested and is in conformity with the standard IEC 62133(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).
	Exposure time	0.05~1.0sec (in 0.01 second increments)	0.05 - 1.0 seconds in 0.01 increments	**Identical**
	mA	3 mA	2.5 mA fixed	**Identical, Justification for Identical :** The Performance Bench Testing demonstrated that these

				differences do not raise new questions of safety and effectiveness in comparison with the predicate device.
	kVp	70 kV XERO α	60 or 65 kVp fixed	**Identical**
	Waveform	Constant Potential (DC)	Constant Potential (DC)	**Identical**
	Applied Standard	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-65	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-65	**Identical**

There are no significant differences between the XERO α and the predicate device that would have a negative impact on the product's use. Therefore, the subject device is considered substantially equivalent to the predicate device.

9. Summary of Non-Clinical Data [21 CFR 807.92(b)(1)]

The XERO α comply with the following international and FDA-recognized consensus standards list in Table 2.

Table 2. International and FDA-recognized consensus standards

Standards development organization, reference number, and date	Standard name
ISO 14971: Third Edition 2019-12	Medical devices - Application of risk management to medical devices
IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
IEC 60601-2-65 Edition 1.2 2021-05 CONSOLIDATED VERSION	Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes

And XERO α comply with the FDA guidance documents listed in Table 3.

Table 3. FDA Guidance Documents

Title of Guidance Document	Issue Date
Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	July 28, 2014
Content of Premarket Submissions for Device Software Functions, Guidance for Industry and Food and Drug Administration Staff	June 14, 2023
Guidance for Industry and Food and Drug Administration Staff: Medical X-Ray Imaging Devices Conformance with IEC Standards	May 8, 2019
Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff	November 28, 2017

The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The test results support that all the specifications have met the acceptance criteria. Verification and validation testing were found acceptable to support the claim of substantial equivalence.

10. Summary of Clinical Data [21 CFR 807.92(b)(2)]

Not Applicable
Clinical studies are unnecessary to validate the safety and effectiveness of the Stationary x-ray system, XERO α, the subject of this 510(k) notification.

11. Conclusion [21 CFR 807.92(b)(3)]

The XERO α is substantially equivalent to the currently marketed predicate device (K200182) in terms of technical characteristics, general function, application and indications for use, safety, and effectiveness.

Substantial equivalence for Hand-held intraoral dental x-ray equipment(XERO α) was demonstrated through the non-clinical performance in compliance with the requirements specified in the international and FDA recognized consensus standards, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62366-1, IEC 60601-2-65 and IEC 62304.

The comparison of technological characteristics, non-clinical performance data and safety testing demonstrate that the XERO α is substantially equivalent to the predicate devices.