HDX WILL Corp.
℅ Myoung-Joon Lee
General Manager
#105,106,201,202,203,204, 38, Osongsaengmyeong
4-ro Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheonbuk-do 28161
REPUBLIC OF KOREA

December 27, 2019

Re: K192700
Trade/Device Name: Xcam
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: November 8, 2019
Received: November 13, 2019

Dear Myoung-Joon 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)*
K192700

Device Name
Xcam

Indications for Use *(Describe)*
This X-ray Unit is intended to be used in portable applications, by a qualified/trained dentist or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of dental structures.

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 - K192700

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

November 8th, 2019

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

- Name of Manufacturer: HDX WILL CORP.
- Address: #105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Republic of Korea
- Contact Person: Myoung-Joon Lee / General Manager
- Telephone No.: +82-43-710-7318
- Fax No.: +82-43-710-7312
- Email Address: mjlee@iwillmed.com
- Registration No.: 3013511605

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

Device Name	Xcam
Regulation Number	21 CFR 872.1800
Common/Usual Name	Portable Dental X-ray System
Regulatory Class	Class II
Product Code	EHD
Classification Name	Unit, X-Ray, Extraoral With Timer
Panel	Radiology

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

The identified predicate devices within this submission are shown as follow;

Predicate device

- 510(k) Number:	K132041
- Applicant:	POSDION CO., LTD.
- Device Name:	REXTAR X
- Regulation Number:	21 CFR 872.1800
- Regulation Name:	Extraoral source x-ray system
- Regulatory Class:	Class II
- Product Code:	EHD
- Classification Name:	Unit, X-Ray, Extraoral With Timer

There are no significant differences between the Xcam and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in technical characteristics, output characteristics and operation mode.

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

The Xcam is a portable X-ray for taking diagnostic radiographic exposures of body parts and operates on 11.1V DC supplied by a battery.
Xcam is composed of x-ray generator including x-ray tubes, equipment controller, power controller, user interface and x-ray collimator. Xcam can be used with an imaging sensor.
The image receptor, necessary component for a fully functional x-ray system, is not part of the submitted device.

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

This X-ray Unit is intended to be used in portable applications, by a qualified/trained dentist or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of dental structures.

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7. Determination of Substantial Equivalence

Summary of technological characteristics of the device compared to the predicate device. [21 CFR 807.92(a)(6)]

a) Technological Characteristics

Applicant	HDX WILL CORP.	POSDION CO., LTD.	SE Note
Device Name	Xcam	Rextar X	
	Subject Device	Predicate Device	-
510(k) Number	K192700	K132041	-
Common/Usual Name	Portable Dental X-ray System	Portable X-ray System	-
Regulation Number	872.1800	872.1800	-
Product Code	EHD	EHD	-
Class	Class II	Class II	-
Model	Xcam	Rextar X	-
Indications for Use	This X-ray Unit is intended to be used in portable applications, by a qualified/trained dentist or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of dental structures.	REXTAR X is a portable X-ray system 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.	Similar
Dimension (Length x Height x Width)	167.51 mm x 127.55 mm x 97.05 mm	146 mm x 155 mm x 139 mm	Similar
Weight	1.8 kg	2 kg	Similar
Energy Source	11.1 VDC	11.1 VDC	Same
Battery Type	Rechargeable	Rechargeable	Same
Display	LCD Panel Display	LCD Panel Display	Same
Tube Voltage	70 kV	70 kV	Same
Tube Current	2 mA	2 mA	Same
Exposure Time	0.05-1.3 s (39 steps)	0.01-1.30 sec (43 steps)	Similar
Inherent Filtration	At least 1.0 mm Al	At least 1.0 mm Al	Same
Total Filtration	At least 1.5 mm Al	At least 1.5 mm Al	Same
Focal Spot Size	0.4 mm	0.4 mm	Same
Anode Material	Tungsten	Tungsten	Same
Target Angle	12.5°	12°	Similar
Compatible with Digital Imaging	Applicable	Applicable	Same

b) Substantial Equivalence Discussion

There are no significant differences between the Xcam and the predicate device that would adversely affect the use of the product. It is substantially equivalent to these devices in technical characteristics, output characteristics and operation mode.

8. Non-Clinical Test Summary

The Xcam complies with voluntary standards for electrical safety, electromagnetic compatibility. The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety, Electromagnetic Compatibility and Performance:
The Xcam complies with the electrical safety and electromagnetic compatibility requirements established by the standards.

- Electrical Basic Safety and Essential Performance requirements in accordance with ES60601-1
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2
- Radiation Protection In diagnostic X-Ray Equipment requirements of IEC 60601-1-3
- Dental Intra-Oral X-Ray Equipment requirements of 60601-2-65

The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, and 1020.31. The records are available for review.

2) Software Validations
The Xcam use original software. The Xcam contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.
Software information is provided in accordance with FDA guidance: “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005.”
Cybersecurity information is provided in accordance with FDA guidance: “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, issued on October 2, 2014”

3) Biocompatibility

A biocompatibility study is not necessary and proper device cleaning is sufficient to address any health concerns.

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

The Xcam has same indications for use and technical characteristic to the predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness. In addition, performance testing conducted demonstrate that the subject device is as safe as effective as the predicate. Therefore, the subject device is substantially equivalent to the predicate device.