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

March 15, 2019

Re: K190357
Trade/Device Name: Star-X, Intraoral X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: February 14, 2019
Received: February 15, 2019

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K190357

Device Name
Star-X; Intraoral X-ray System

Indications for Use *(Describe)*
Star-X is intra-oral X-ray system for dental diagnosis that can radiate X-ray images by irradiating X-rays generated by high voltage to an anode in an X-ray tube and reacting with the receptor (film, sensor).

Star-X is a dental X-ray equipment (extra-oral source system) intended for use by qualified dentist or dental technician for both adult and pediatric patient for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.

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

[As required by 21 CFR 807.92]

K190357

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

March 11th, 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, Korea
- Contact Person: Myoung-Joon Lee / General Manager
- Telephone No.: +82-43-710-7318
- Fax No.: +82-43-710-7312
- Email Address: mjlee@iwllmed.com
- Registration No.: 3013511605

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

Device Name	Star-X; Intraoral X-ray System
Regulation Number	21 CFR 872.1800
Common/Usual Name	Extraoral source 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 #1

- 510(k) Number: K970975
- Applicant: PLANMECA OY
- Device Name: PROSTYLE INTRA (PLANMECA INTRA)
- 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

Predicate device #2

- 510(k) Number: K042260
- Applicant: TAKARA BELMONT USA, INC.
- Device Name: PHOT-X II, MODEL 303
- 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 Star-X 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 Star-X is an X-ray generator for dental intra-oral X-ray imaging and intended to be used for producing diagnostic dental radiographs for treatment of disease of teeth, jaw and oral structures. The Star-X is consisted of X-ray generator, beam limiting device (cone), control panel, mechanical arm, support device, chair and backrest. The control panel allows for accurate exposure control and adjustable arm provide for convenient patient positioning.

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

Star-X is intra-oral X-ray system for dental diagnosis that can radiate X-ray images by irradiating X-rays generated by high voltage to an anode in an X-ray tube and reacting with the receptor (film, sensor).

Star-X is a dental X-ray equipment (extra-oral source system) intended for use by qualified dentist or dental technician for both adult and pediatric patient for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.

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.	PLANMECA OY	TAKARA BELMONT USA, INC.	SE Note
Device Name	Star-X	PROSTYLE INTRA (PLANMECA INTRA)	PHOT-X II, MODEL 303	
	Subject Device	Predicate Device #1	Predicate Device #2	-
510(k) Number	K190357	K970975	K042260	-
Common/Usual Name	Extraoral source x-ray system	Extraoral source x-ray system	Extraoral source x-ray system	-
Regulation Number	872.1800	872.1800	872.1800	-
Product Code	EHD	EHD	EHD	-
Class	Class II	Class II	Class II	-
Model	Star-X	PROSTYLE INTRA	Model 303	-
Indications for Use	Star-X is intra-oral X-ray system for dental diagnosis that can radiate X-ray images by irradiating X-rays generated by high voltage to an anode in an X-ray tube and reacting with the receptor (film, sensor). Star-X is a dental X-ray equipment (extra-oral source system) intended for use by qualified dentist or dental technician for both adult and pediatric patient for producing diagnostic dental radiographs for treatment of diseases of the teeth, jaw, and other oral structures using intra-oral image receptors.	The Planmeca Prostyle Intra X-ray Unit is an extraoral source X-ray system, which is intended for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The Prostyle Intra is intended to be used with intraoral film, either hold in place by the patient with finger or placed to a film holder which is pressed between the teeth. The use of the device is allowed only under supervision of a dentist.	PHOX-X II MODEL 303 is a extraoral source dental radiographc x-ray unit. This unit works as a diagnostic purpose x-ray source for human teeth with the resultant image recorded on intraoral dental x-ray film or image receptor. The design, function and positioning of the x-ray unit is similar to most all other x-ray machines manufactured for this specific purpose over the past thirty years.	Same
Mechanical				
Mechanical configuration	Floor-mounted type	Wall-mounted type	Wall-mounted type	Similar
Minimum Source to skin distance	> 200 mm	200 mm (Regular cone) 300 mm (Long cone)	203 mm (Regular cone) 305 mm (Long cone)	Similar
Electrical & X-ray tube assembly				
Rated mains voltage	100-120/200-240 VAC	110-115 VAC	120 VAC	Similar
Tube Voltage	65 kV	50, 53, 55, 57, 60, 63, 66, 70 kV	60 or 70 kV	Similar
Tube Current	3 or 6 mA	8 mA	4 or 7 mA	Similar

Exposure Time	0.01-3.2 s (in 0.01 step)	0.01-3.2 sec (23 steps)	0.01-3.2 s (23 steps)	Same
Inherent filtration	0.8 mm Al	1.0 mm Al Equivalent at 70 kV	1.7 mm Al Equivalent	Similar
Total Filtration	> 1.8 mm Al	2.0 mm Al Equivalent at 70 kV	2.0 mm Al Equivalent at 70 kV	Similar
Focal Spot Size	0.8 mm	0.7 mm x 0.7 mm	0.7 mm x 0.7 mm	Similar
Anode Material	Tungsten	Tungsten	Tungsten	Same
Compatible with Digital Imaging	Applicable	Applicable	Applicable	Same
Duty Cycle	1:60	1:15	1:50	Similar

b) Substantial Equivalence Discussion

There are no significant differences between the Star-X 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 Star-X 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 Star-X 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 Star-X use original software. The Star-X 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 disinfection is sufficient to address any health concerns.

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

The Star-X 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 devices.