October 19, 2021

HDX Will Corp.
℅ Kaon Kim
Junior Manager, Regulatory Affairs
#105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro
Osong-eup, Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
REPUBLIC OF KOREA

Re: K212254
Trade/Device Name: DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: July 20, 2021
Received: July 22, 2021

Dear Kaon 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,

, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212254

Device Name
DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)

Indications for Use *(Describe)*
The DENTRIα series is a Computed Tomography X-Ray imaging device specialized in diagnosing general dental treatments and orthodontic purpose using Panoramic and Cephalometric images respectively. In addition DENTRIα series is used in the field of Otolaryngology by capturing 360 degree rotation sequence of the head and neck areas, including the ENT and dentomaxillofacial areas for a dental treatment in adult and pediatric dentistry and obtains x-ray images from different angles and calculate through computer-processed to produce 3D x-ray tomographic images. The DENTRIα series used by physicians, dentists, and x-ray technologists.

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]

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

October 14th, 2021

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: Kaon Kim / Junior Manager
- Telephone No.: +82-43-710-7318
- Fax No.: +82-43-710-7312
- Email Address: kaonkim@iwillmed.com
- Registration No.: 3013511605

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

Device Name	DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)
Regulation Number	21 CFR 892.1750
Regulation Name	Computed tomography x-ray system
Common/Usual Name	Dental X-ray System
Regulatory Class	Class II
Product Code	OAS
Classification Name	X-Ray, Tomography, Computed, Dental
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:	K160140
- Applicant:	HDX WILL Corp.
- Device Name:	DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)
- Regulation Number:	21 CFR 892.1750
- Regulation Name:	Computed tomography x-ray system
- Regulatory Class:	Class II
- Product Code:	OAS
- Classification Name:	X-Ray, Tomography, Computed, Dental

There are no significant differences between the DENTRIα series 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)]

This Equipment is a Dental X-Ray imaging device used for diagnostic purpose in dental treatment. The operating principle of this device is obtaining the tomographic, and panoramic images by rotating arm to get the recombination data. X-ray generator and detector rotate around the patient to irradiate the X-ray, and penetrated X-ray is measured by the detector. When the X-ray is irradiated on the teeth area for instance, large amount of X-ray is attenuated because objects such as bones are highly dense. On the contrast, X-ray is more permeable to small molecules with low density such as skin or tissue, so more X-ray would pass through the subject. By measuring data obtained from measuring the X-ray is reconstructed by the software to display and analyze the anatomical structure for the diagnosis purposes.

1) The DENTRIα series is classified as shown below:

DENTRIα: CT Mode + Panorama Mode + Model Scan Mode
DENTRI-Cα: CT Mode + Panorama Mode + Model Scan Mode + Cephalo Mode (One-shot)
DENTRI-Sα: CT Mode + Panorama Mode + Model Scan Mode + Cephalo Mode (Scan)

MODEL		CT	Panorama	Cephalo		Model Scan (Optional)	Cu Filter (Optional)
				One-shot	Scan		
DENTRIα	Stitch (Option)	●	●	-	-	●	●
	Non-Stitch (Option)	●	●	-	-	●	●
DENTRI-Cα	Stitch (Option)	●	●	●	-	●	●
	Non-Stitch (Option)	●	●	●	-	●	●
DENTRI-Sα	Stitch (Option)	●	●	-	●	●	●
	Non-Stitch (Option)	●	●	-	●	●	●

2) Description of the image detectors used.

Model	DENTRIα, DENTRI-Cα, DENTRI-Sα		DENTRI-Cα	DENTRI-Sα
Contents	CT / Panorama/ Model Scan		Cephalo (One-shot type)	Cephalo (Scan type)
Detector model	Xineos-1313 (Optional)	FXDD-0606CA (Optional)	FLAATZ 330N	Xineos-2301 / Xineos-2301S
Manufacturer	Teledyne DALSA	Vieworks Co., Ltd.	DR Tech	Teledyne DALSA
Detector type	CMOS (Complementary metal oxide semiconductor)	TFT: a-Si (Thin-Film Transistor, Amorphous Silicon)	TFT: a-Se (Thin-Film Transistor, Amorphous Selenium)	CMOS (Complementary metal oxide semiconductor)
Resolution (pixels)	1316 x 1312	1256 x 1256	2048 x 1536	2304 x 68
Pixel size (um)	100.1	119	129.0	99.0
MTF	57% at 1 lp/mm	60% at 1 lp/mm	83.3% at 2 lp/mm	65% at 1 lp/mm
DQE	70% at 0 lp/mm	60% at 1 lp/mm	38.5% at 0 lp/mm	57% at 1 lp/mm
Active area (mm)	131 x 131	149.464 x 149.464	198 x 264	228 x 6.7
A/D Conversion	14 bits	16 bits	14 bits	14 bits
FDA 510(k) number	Not Known	Not Known	Not Known	Not Known
510(k) cleared device including corresponding detector as a component	1) System name: DENTRIα, DENTRI-Cα, DENTRI-Sα 2) Manufacturer: HDX WILL Corp. 3) 510(k) number: K160140	1) System name: RCT800 2) Manufacturer: Ray Co., Ltd. 3) 510(k) number: K192737	1) System name: DENTRIα, DENTRI-Cα, DENTRI-Sα 2) Manufacturer: HDX WILL Corp. 3) 510(k) number: K160140	Xineos-2301: 1) System name: DENTIOIII, DENTIOIII-S 2) Manufacturer: HDX WILL Corp. 3) 510(k) number: K181297 Xineos-2301S: Not known

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

The DENTRIα series is a Computed Tomography X-Ray imaging device specialized in diagnosing general dental treatments and orthodontic purpose using Panoramic and Cephalometric images respectively. In addition DENTRIα series is used in the field of Otolaryngology by capturing 360 degree rotation sequence of the head and neck areas, including the ENT and dentomaxillofacial areas for a dental treatment in adult and pediatric dentistry and obtains x-ray images from different angles and calculate through computer-processed to produce 3D x-ray tomographic images. The DENTRIα series used by physicians, dentists, and x-ray technologists.

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.**		**HDX WILL Corp.**	**SE Note**
Device Name	**DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)**		**DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)**	
	Subject Device		Predicate Device	-
510(k) Number	K212254		K160140	-
Common/Usual Name	Dental X-ray System		Dental X-ray System	-
Regulation Number	892.1750		892.1750	-
Product Code	OAS		OAS	-
Class	Class II		Class II	-
Model	DENTRIα, DENTRI-Cα, DENTRI-Sα		DENTRIα, DENTRI-Cα, DENTRI-Sα	-
Indications for Use	The DENTRIα series is a Computed Tomography X-Ray imaging device specialized in diagnosing general dental treatments and orthodontic purpose using Panoramic and Cephalometric images respectively. In addition DENTRIα series is used in the field of Otolaryngology by capturing 360 degree rotation sequence of the head and neck areas, including the ENT and dentomaxillofacial areas for a dental treatment in adult and pediatric dentistry and obtains x-ray images from different angles and calculate through computer-processed to produce 3D x-ray tomographic images. The DENTRIα series used by physicians, dentists, and x-ray technologists.		The DENTRIα series is a Computed Tomography X-Ray imaging device specialized in diagnosing general dental treatments and orthodontic purpose using Panoramic and Cephalometric images respectively. In addition DENTRIα series is used in the field of Otolaryngology by capturing 360 degree rotation sequence of the head and neck areas, including the ENT and dentomaxillofacial areas for a dental treatment in adult and pediatric dentistry and obtains x-ray images from different angles and calculate through computer-processed to produce 3D x-ray tomographic images. The DENTRIα series used by physicians, dentists, and x-ray technologists.	Same
Operation Mode	1. CT 2. Panorama 3. Cephalo 1) One-Shot type 2) Scan type 4. Model Scan		1. CT 2. Panorama 3. Cephalo 1) One-Shot type 2) Scan type	Similar
X-ray tube assembly				
X-ray tube assembly options	PXD-140CT (Optional)	WDG90 (Optional)	PXD-140CT	-
X-ray tube	OPX/105 (C.E.I.)	OX/115-05 (C.E.I.)	OPX/105 (C.E.I.)	Similar
Target angle	5°	15°	5°	Similar
Focal spot size according to IEC 60336, measured in the central X-ray beam	0.5 mm	0.5 mm	0.5 mm	Same

Inherent filtration according to IEC 60522	0.5 mmAl	0.5 mmAl	0.5 mmAl	Same
Anode material	Tungsten	Tungsten	Tungsten	Same
Total filtration of X-ray tube assembly	> 2.5 mmAl > 2.5 mmAl + 0.5 mmCu (Optional)		> 2.5 mmAl	Similar
Range of X-ray Tube Voltage settings	PXD-140CT (Optional) 1. CT 60-110 kV ±8% 2. Panorama 60-90 kV ±8% 3. Cephalo 1) One-Shot type 60-110 kV ±8% 2) Scan type 60-90 kV ±8%	WDG90 (Optional) 1. CT 60-90 kV ±8% 2. Panorama 60-90 kV ±8% 3. Cephalo 1) One-Shot type 60-90 kV ±8% 2) Scan type 60-90 kV ±8%	1. CT 60-110 kV ±8% 2. Panorama 60-90 kV ±8% 3. Cephalo 1) One-Shot type 60-110 kV ±8% 2) Scan type 60-90 kV ±8%	Same
Range of X-ray Tube Current settings	4-10 mA ±10%		4-10 mA ±10%	Same
Range of Irradiation Time settings	1. CT 8.0-36.0 s ± (5 % + 50 ms) 2. Panorama 1.2-14.0 s ± (5 % + 50 ms) 3. Cephalo 1) One-Shot type 0.5 s to 2.0 s ± (5 % + 50 ms) (in 0.5 s increments) 2) Scan type 2.5-8.0 s ± (5 % + 50 ms) 4. Model Scan 24 s		1. CT(Normal) 8 s or 24 s ± 10 % 2. Panorama 14 s and less ± 10 % 3. Cephalo 1) One shot type 0.5, 1, 1.5, 2 s ± 10 % 2) Scan type 8.2 s and less ± 10 %	Similar
Image Properties				
Detector type	1. CT CMOS or TFT:a-Si 2. Panorama CMOS or TFT:a-Si 3. Cephalo 1) One-shot type TFT:a-Se 2) Scan type CMOS		1. CT Flat panel 2. Panorama Flat panel 3. Cephalo 1) One shot type Flat panel 2) Scan type CCD	Similar
Pixel size	1. CT 100.1 um or 119 um 2. Panorama 100.1 um or 119 um 3. Cephalo 1) One-shot type 129.0 um 2) Scan type 99.0 um		1. CT: 100.1 or 127 ㎛ 2. Panorama: 100.1 or 127 ㎛ 3. Cephalo 1) One shot type: 129 ㎛ 2) Scan type: 27 ㎛	Similar
Active area (mm)	1. CT 131 x 131 or 149.464 x 149.464 2. Panorama 6 x 130 or		1. CT: 131 x 131 mm or 130 x 130 mm 2. Panorama: 6 x 131 mm or	Similar

	6 x 149.5 3. Cephalo 1) One-shot type 198 x 264 2) Scan type 6.7 x 228	3.94 x 128.78 mm 3. Cephalo 1) One shot type: 193 x 259 mm 2) Scan type: 6.9 x 221 mm	
MTF	1. CT: - 57% at 1 lp/mm or - 60% at 1 lp/mm 2. Panorama: - 57% at 1 lp/mm or - 60% at 1 lp/mm 3. Cephalo 1) One shot type - 83.3% at 2 lp/mm 2) Scan type: - 65% at 1 lp/mm	1. CT: - 57% at 1 LP/mm or - 55% at 1 LP/mm 2. Panorama: - 57% at 1 LP/mm or - 55% at 1 LP/mm 3. Cephalo 1) One shot type: - 83.3% at 2 LP/mm 2) Scan type: - 70% at 1 LP/mm	Similar
DQE	1. CT: - 70% at 0 lp/mm or - 60% at 1 lp/mm 2. Panorama: - 70% at 0 lp/mm or - 60% at 1 lp/mm 3. Cephalo 1) One shot type - 38.5% at 0 lp/mm 2) Scan type: - 57% at 1 lp/mm	1. CT: - 70% at 0 LP/mm or - 58% at 1 LP/mm 2. Panorama: - 70% at 0 LP/mm or - 58% at 1 LP/mm 3. Cephalo 1) One shot type: - 38.5% at 0 LP/mm 2) Scan type: - 50% at 0 LP/mm	Similar
Geometry			
Source Image Distance (SID)	1. CT 600 mm 2. Pano 560 mm 3. Cephalo 1) One-Shot Ceph 1792 mm 2) Scan Ceph 1,782 mm	1. CT 600 mm 2. Panorama 560 mm 3. Cephalo 1) One shot type 1790 mm 2) Scan type 1783 mm	Similar
Format Compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	Same

b) Substantial Equivalence Discussion

The DENTRIα series is substantially equivalent to the predicate device identified above with respect to intended use, principles of operation, and technological characteristics. From the information provided in table above, it is understood that the subject device does not introduce any new technology and/or indications of use. Therefore, the DENTRIα series is considered substantially equivalent to the predicate device.

8. Non-Clinical Test Summary

The DENTRIα series is verified and validated according to the FDA design control requirements, 21 CFR 820. The subject device had been subjected to the applicable safety and performance testing before release to ensure the device meets all its specifications. The quality assurance measures applied to the design and development of the subject device include, but not limited to risk analysis, verification and validation, product specifications and design reviews.

1) Thermal, electrical, mechanical safety & Electromagnetic Compatibility

The DENTRIα series complies with the electrical safety and electromagnetic compatibility requirements established by the standards below:

- 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 Extra-Oral X-Ray Equipment requirements of IEC 60601-2-63

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 DENTRIα series utilizes original software and OTS software as an image viewer. The DENTRIα series contains MODERATE level of concern software. Software was designed and developed according to a software development process and was verified and validated.
The algorithm type of image reconstruction is FBP (Filtered Back Projection).

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 test is not necessary when considering the device’s characteristics.

4) Performance Test

Bench testing was used to assess whether the parameter measured required for describing functionalities related to the dental X-ray device’s imaging properties meet the criteria under the designated tolerance.
Image performance testing was conducted according to IEC 61223-3-4 standard. The test results show that the DENTRIα series met all requirements of the standard.

5) SSXI (Solid State X-ray Imaging) Devices Report

Non-clinical performance was conducted for imaging performance of the proposed detector in accordance with FDA guidance: “Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, issued on September 1, 2016”.
MTF (Modulation Transfer Function) and DQE (Detective Quantum Efficiency) were tested, measured, and compared with the detectors of the predicate devices in terms of detector type, pixel size, active area, MTF and DQE, the diagnostic image quality of the detector is equal or better than those of the predicate devices based on the Non-clinical test results. Therefore, there are no significant differences in the safety and performance of the detectors.

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

In conclusion, the conducted tests, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the DENTRIα series meet applicable requirements and standards for its safety and effectiveness for the intended use. The testing and validation activities conducted demonstrate that any differences between the subject device and the predicate devices do not raise new or different questions of safety or effectiveness compared to the predicate devices. Therefore, the DENTRIα series is substantially equivalent to the predicate devices.