December 30, 2021

HDX WILL Corp.
℅ Jeon Seunghwa
Manager
10F, 29, Insadong 5-gil
Jongno-gu, Seoul 03162
SOUTH KOREA

Re: K211159
    Trade/Device Name: eco-x Series (eco-x, eco-x-s)
    Regulation Number: 21 CFR 892.1750
    Regulation Name: Computed tomography x-ray system
    Regulatory Class: Class II
    Product Code: OAS
    Dated: April 15, 2021
    Received: April 19, 2021

Dear Jeon Seunghwa:

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)*
K211159

Device Name
eco-x series (eco-x, eco-x-s)

Indications for Use *(Describe)*
'eco-x series (eco-x, eco-x-s)' is 4 in 1 digital equipment that provides CT, Panoramic, Cephalometric, and Model Scan images by using X-Ray scan. It provides 2D images for diagnosing cranial bone tissue including adult and pediatric teeth, jaw, oral structures and skull. Also, it provides 3D images by reconstructing images acquired by capturing cervical bone and occipital regions.

In addition, 'eco-x series' is used as diagnosis for general and/or orthodontic treatment, and also is intended to use for ENT (Ear, Nose, and Throat) and dentomaxillofacial diagnosis.

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.

510(K) Summary
K211159

510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.

Date Prepared: Apr. 15. 2021

K-number: K211159

1. Submitter

- 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

- Telephone No.   : +82-43-710-7318 (Fax: +82-43-710-7312)

- Contact Information   : Jeon, Seunghwa / Manager, HDX WILL CORP. 10F, 29, Insadong 5-gil, Jongno-gu, Seoul, 03162, Korea Tel: +82-2-2003-5023 Email : shjeon2@iwillmed.com

2. Device Name and Classification

- Trade Name   : eco-x Series (eco-x, eco-x-s)

- Regulation Name   : Computed Tomography X-ray System

- Device Classification   : Class II

- Product Code   : OAS

- Regulation Number   : 21 C.F.R. § 892.1750

- Classification Panel   : Radiology

3. Predicate Device

The predicate devices of the subject device are as follows;

Predicate Device #1

- K Number   : K160140

- Manufacturer   : HDX WILL CORP..

- Trade/Device Name   : DENTRIα Series (DENTRIα, DENTRI-Cα, DENTRI-sα)

- Device Classification   : Class II

- Product Code   : OAS
- Regulation Number   : 21 C.F.R. § 892.1750
- Regulation Name   : Computed tomography x-ray system
- Classification Panel   : Radiology

Predicate Device #2

- K Number   : K093590
- Manufacturer   : PLANMECA OY
- Trade/Device Name   : PLANMECA PROMAX 3D MAX
- Device Classification   : Class II
- Product Code   : MUH
- Regulation Number   : 21 C.F.R. § 872.1800
- Regulation Name   : Extraoral source x-ray system
- Classification Panel   : Radiology
- K Number   : K093590

We are not aware of any design-related recalls regarding the predicate devices. No reference devices were used in this submission.

4.   Device Description

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 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 eco-x Series are classified as shown below.

		eco-x	eco-x-s
Mode	CBCT	●	●
	Model Scan	●	●
	PANO	●	●
	[1] CEPH (SCAN)	-	●
Added filter (Cu filter)		0.2 mm	
[2] Collimator	1-axis	●	●
	4-axis	●	●
Note 1: Detector for CEPH is provided as optional (Xineos-2301S or Pluto0900X) Note 2: One collimator can be assembled to the device according to the user's choice.			

- CBCT: Capture mode for acquiring CT image. It enables to select the preferable range of capture among below and acquire image.
  - ■ Free FOV
  - ■ Dental Arch
  - ■ Nose
  - ■ Ear

- PANO (Panorama): Capture mode for acquiring Panoramic image. It enables to select the preferable range of capture among below and acquire image.
  - ■ Teeth
  - ■ TMJ

- CEPH (Cephalo): Capture mode for acquiring Cephalometric image. It enables to select the preferable range of capture among below and acquire image.
  - ■ LA
  - ■ Frontal (PA)
  - ■ Carpus
  - ■ Waters View
  - ■ SMV

- Model Scan: Capture mode for acquiring Cephalometric image. It enables to select material of model among below and acquire image.
  - ■ Impression scan
  - ■ Stone model scan

The eco-x Series consists of 2 different models. The eco-x-s supports cephalometric scan compared with the eco-x, which do not support CEPH mode.

2) FOV Option for CBCT Mode

CT FOV (Field of View) option in the eco-x Series is as follows:

① FXDD-0606CA (unit: cm)

Mode	Patient type	*Collimator type	
		1-axis collimator	4-axis collimator
Free FOV	For Child	Min. 3x3 – Max. 10x8	Min. 3x3 – Max. 10x8
	For Adult	Min. 3x3 – Max. 12x9	Min. 3x3 – Max. 12x9
Dental Arch	For Child	10x8	10x8
	For Adult	16x9	16x9
Nose	For Child	10x8	10x8
	For Adult	16x9	16x9
Ear	For Child	16x9	14x7
	For Adult	16x9	16x9

* There are 2 types of collimators. One is a 1 axis collimator with a fixed beam limiting size, and the other is a 4-axis collimator that could adjust the beam limiting size. Depending on the user's choice, one collimator among these is assembled to the device and provided.

3) Compatible 3D Viewer Program (Optional)

- Will3D (K Number: K170180)
- OnDemand3D (K Number: K070464)
- InVivoDental (K Number: K123519)

4) Description of the image detectors used.

Model	eco-x, eco-x-s	eco-x-s	
Contents	CBCT / PANO /Model Scan	CEPH	
Detector model	FXDD-0606CA	Xineos-2301S	Pluto0900X
Manufacturer	VIEWORKS	Teledyne DALSA	iRay Technology Co. LTD.
Detector type	TFT:a-si (CSI) Flat panel detector	CMOS Flat panel detector	CMOS
Resolution (pixels)	1495 x 1495	2305 x 68	2252 x 68
Pixel size (μm)	119	99.0	100
MTF	55%-60% at 1 LP/mm	60% at 1LP/mm	55% at 1LP/mm
DQE	55%-60% at 1 LP/mm	57% at 1LP/mm	50% at 1LP/mm
Active area (mm)	149.5 x 149.5	152.0 x 7.0	250 x 7
A/D Conversion	16 bits	14 bits	16 bits
FDA 510(k) Number	No	No	No
510(k) cleared device including corresponding detector as a component	1) System name: RCT800 2) Manufacturer: RAY CO., Ltd 3) 510(K) Number: K192737	Xineos-2301S: Not known	No

The eco-x Series in intended to communicate with the Workstation for the transmission of data through Ethernet cable and RS232 Cable. The CBCT system of eco-x Series does not have any wireless option for the transmission of data.

5) Laser

The laser is used for patient positioning and is classified as Class A. This technical characteristic is as follows:

1. Optical output : 1mW or less
2. Wavelength : 655nm
3. Line type : Accurate Straight

5. Indications for Use

'eco-x series (eco-x, eco-x-s)' is 4 in 1 digital equipment that provides CT, Panoramic, Cephalometric, and Model Scan images by using X-Ray scan. It provides 2D images for diagnosing cranial bone tissue including adult and pediatric teeth, jaw, oral structures and skull. Also, it provides 3D images by reconstructing images acquired by capturing cervical bone and occipital regions.

In addition, 'eco-x series' is used as diagnosis for general and/or orthodontic treatment, and also is intended to use for ENT (Ear, Nose, and Throat) and dentomaxillofacial diagnosis.

6. Technological Comparison to Predicate Devices

Table 1: Technological Comparison of Subject Device (i.e., eco-x Series and Predicate Device #1(K160140))

	Proposed Device	**Predicate Device #1**
K Number	K211159	K160140
Model	eco-x Series (eco-x, eco-x-s)	DENTRIα Series
Manufacturer	HDX WILL CORP.	HDX WILL CORP.
Intended Use	'eco-x series (eco-x, eco-x-s)' is 4 in 1 digital equipment that provides CT, Panoramic, Cephalometric, and Model Scan images by using X-Ray scan. It provides 2D images for diagnosing cranial bone tissue including adult and pediatric teeth, jaw, oral structures and skull. Also, it provides 3D images by reconstructing images acquired by capturing cervical bone and occipital regions. In addition, 'eco-x series' is used as diagnosis for general and/or orthodontic treatment, and also is intended to use for ENT (Ear, Nose, and Throat) and dentomaxillofacial diagnosis.	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, and obtains x-ray images from different angles and calculate though computer-processed to produce 3D x-ray tomographic images. The DENTRIα Series is used by physicians, dentists, and x-ray technologists.
Operation Mode	1) CT 2) Panorama 3) Cephalo (Scan type)	1) CT 2) Panorama 3) Cephalo ・One shot type ・Scan type
X-ray tube assembly		
X-ray tube	OX/115-05	OPX/105 (C.E.I. X-ray tube)
Focal spot size	0.5 mm	0.5 mm
Target angle	15°	5°
Permanent filtration	0.5mmAl	0.5 mmAl (IEC 60522)

	Proposed Device	**Predicate Device #1**
Total filtration of X-ray tube assembly	1) PANO, CEPH: >2.5mmAl 2) CBCT: 　• 　>2.5mmAl + 0.2mm Cu (≥5.3mmAl at 75kV)	> 2.5 mmAl
Anode material	Tungsten	Tungsten
Range of X-ray tube voltage settings	60 - 90 kV	1) CT: 60 - 110 kV± 8 % 2) Panorama: 60 - 90 kV± 8 % 3) Cephalo 　・One shot type: 60 - 110 kV± 8 % 　・Scan type: 60 - 90 kV± 8 %
Range of X-ray tube current settings	4 - 10mA ± 10 %	4 - 10mA ± 10 %
range of irradiation time settings	1) CT(Normal): 8 s, 12 s or 24 s ± 10 % 2) Panorama: 1.2-14 s ± 10 % 3) Cephalo: 　・　Scan type: 2.6-8 s ± 10 %	1) CT(Normal): 8 s or 24 s ± 10 % 2) Panorama: 14 s and less ± 10 % 3) Cephalo 　・One shot type: 0.5, 1, 1.5, 2 s ± 10 % 　・Scan type: 8.2 s and less ± 10 %
Image Properties		
Detector type	1) CT, Panorama: a-si TFT or IGZO-TFT 2) Cephalo: CMOS	1) CT, Panorama: Flat panel 3) Cephalo 　・One shot type: Flat panel 　・Scan type: CCD
Pixel size	1) CT, Panorama: 119 or 95 μm 2) Cephalo: 99 or 100 μm	1) CT, Panorama: 100.1 or 127 μm 2) Cephalo 　・One shot type: 129 μm 　・Scan type: 27 μm
Active area (mm)	1) CT, Panorama 　・149.464 x 149.464 mm^2 or	1) CT: 　・131 x 131 mm^2 or

![HDX WILL logo]

#105, 106, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea, Tel: +82-43-710-7318/ Fax: +82-43-710-7312

	Proposed Device	**Predicate Device #1**
	・95.38 x 168.34 mm^2 2) Cephalo 　・228 x 7 mm or 　・250 x 7 mm	・130 x 130 mm 2) Panorama: 　・6 x 131 mm or 　・3.94 x 128.78 mm 3) Cephalo 　・One shot type: 193 x 259 mm 　・Scan type: 6.9 x 221 mm
MTF	1) CT: 　・55%-60% at 1 LP/mm or 　・62%-67% at 1 LP/mm 2) Panorama: 　・55%-60% at 1 LP/mm or 　・62%-67% at 1 LP/mm 3) Cephalo (Scan type) 　・60% at 1 LP/mm 　・55% 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 　・One shot type: 83.3% at 2 LP/mm 　・Scan type: 70% at 1 LP/mm
DQE	1) CT: 　・55%-60% at 1 LP/mm or 　・53%-59% at 1 LP/mm 2) Panorama: 　・55%-60% at 1 LP/mm or 　・53%-59% at 1 LP/mm 3) Cephalo (Scan type) 　・57% at 1 LP/mm 　・50% 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 　・One shot type: 38.5% at 0 LP/mm 　・Scan type: 50% at 0 LP/mm
Geometry		
Source Image Distance (SID)	1) CT, Panorama: 577 mm 2) Cephalo: 1596 mm	1) CT: 600 mm 2) Panorama: 560 mm 3) Cephalo: 　・One shot type: 1790 mm

	Proposed Device	**Predicate Device #1**
		· Scan type: 1783 mm
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Dose Information		
CT Mode	CTDIw=8.28mGy At FOV Ø 16*9 , 0.2mm Cu filter Irradiation parameters :90kV,10mA, 24s	$CTDI_w$ = 11.12mGy (at FOV Ø 10 X 8. Irradiation parameters: 90kV, 10mA)
Panorama	DAP = 280.8 mGy· cm^2 (Irradiation parameters: 80kV, 10mA, 14s)	- Xineos-1313: DAP = 198.8 mGy· cm^2 (Irradiation parameters: 80kV, 10mA, 14s) - PaxScan1313DX: DAP = 119.0 mGy·cm^2 (Irradiation parameters: 80kV, 10mA, 14s)
Cephalo	- Scan type, DAP= 48.6 mGy·cm^2 (Irradiation parameters: 80kV, 10mA, 8s)	One Shot type, DAP = 26.7 mGy·cm^2 (Irradiation parameters: 80kV, 10mA, 0.5s) Scan type, DAP = 21.3 mGy·cm^2 (Irradiation parameters: 80kV, 10mA, 8.2s)

Table 2: Technological Comparison of Subject Device (i.e., eco-x Series and Predicate Device #2 (K093590))

	Proposed Device	**Predicate Device #2**
K Number	K211159	K093590
Model	eco-x Series (eco-x, eco-x-s)	PLANMECA PROMAX 3D MAX
Manufacturer	HDX WILL CORP.	PLANMECA OY
Intended Use	'eco-x series (eco-x, eco-x-s)' is 4 in 1 digital equipment that provides CT, Panoramic, Cephalometric, and Model Scan images by using X-Ray scan. It provides 2D images for diagnosing cranial bone tissue including adult and pediatric teeth, jaw, oral structures and skull. Also, it provides 3D images by reconstructing images acquired by capturing cervical bone and occipital regions. In addition, 'eco-x series' is used as diagnosis for general and/or orthodontic treatment, and also is intended to use for ENT (Ear, Nose, and Throat) and dentomaxillofacial diagnosis.	PLANMECA PROMAX 3D MAX is a three dimensional Cone Beam Volumetric Tomography (CBVT) x-ray system, which is intended to produce three-dimensional images of the human teeth, jaw and skull. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 3D viewing stations. The device is to be operated and used by dentists and other legally qualified health care professionals.
Operation Mode	1) CT 2) Panorama 3) Cephalo (Scan type)	1) 3D 2) Smart Pan 3) Cephalo ・Planmeca ProCeph Scanning Ceph
X-ray tube assembly		
X-ray tube	OX/115-05	Toshiba D-067SB
Focal spot size	0.5 mm	0.6 mm
Target angle	15°	12°
Permanent filtration	0.5mmAl	Inherent Filtration At least 0.8 mm Al at 50 kV
Total filtration of X-ray tube	1) PANO, CEPH: >2.5mmAl 2) CBCT:	1) 3D: > 2.5 mm Al+ 0.5 mm Cu 2) Smart Pan: > 2.5 mm Al 3) Cephalo: > 2.5 mm Al

	Proposed Device	Predicate Device #2
assembly	• >2.5mmAl + 0.2mm Cu (≥5.3mmAl at 75kV)	
Anode material	Tungsten	Tungsten
Range of X-ray tube voltage settings	60 - 90 kV	1) 3D: 60 – 96 kV ± 5 % 2) Smart Pan: 60 – 84 kV ± 5 % 3) Cephalo: 60 – 84 kV ± 5 %
range of X-ray tube current settings	4 - 10mA ± 10 %	1 – 16 mA ± 10 %
Range of irradiation time settings	1) CT(Normal): 8 s, 12 s or 24 s ± 10 % 2) Panorama: 1.2-14 s ± 10 % 3) Cephalo: ・ Scan type: 2.6-8 s ± 10 %	1) 3D: 3.6 – 24 s ± 10 % 2) Smart Pan: 10 s ± 10 % 3) Cephalo: ・Planmeca ProCeph: 0.1 – 0.8 s ± 10 % ・Scanning Ceph: - Normal: 12 – 18.7s ± 10 % ・High Speed: 6.4 – 9.9s ± 10 %
Image Properties		
Detector type	1) CT, Panorama: a-si TFT or IGZO-TFT 2) Cephalo: CMOS	1) 3D: Flat panel 2) Smart Pan: Flat panel 3) Cephalo: ・Planmeca ProCeph: Flat panel ・Scanning Ceph: CCD
Pixel size	1) CT, Panorama: 119 or 95 μm 2) Cephalo: 99 or 100 μm	1) 3D: 127 μm 2) Smart Pan: 127 μm 3) Cephalo: ・Planmeca ProCeph: 139 μm

	Proposed Device	Predicate Device #2
		・Scanning Ceph: 48 μm
Active area (mm)	1) CT, Panorama ・149.464 x 149.464 mm or ・95.38 x 168.34 mm 2) Cephalo ・228 x 7 mm or ・250 x 7 mm	1) 3D: 193 x 242 mm 2) Smart Pan: 13 x 162 mm 3) Cephalo: ・Planmeca ProCeph: 302 x 249 mm ・Scanning Ceph: 6 x 292 mm
MTF	1) CT: ・55%-60% at 1 LP/mm or ・62%-67% at 1 LP/mm 2) Panorama: ・55%-60% at 1 LP/mm or ・62%-67% at 1 LP/mm 3) Cephalo (Scan type) ・60% at 1 LP/mm 　55% at 1 LP/mm	Unknown
DQE	1) CT: ・55%-60% at 1 LP/mm or ・53%-59% at 1 LP/mm 2) Panorama: ・55%-60% at 1 LP/mm or ・53%-59% at 1 LP/mm 3) Cephalo (Scan type) ・57% at 1 LP/mm 　50% at 1 LP/mm	Unknown
Geometry		

	Proposed Device	Predicate Device #2
Source Image Distance (SID)	1) CT, Panorama: 577 mm 2) Cephalo: 1596 mm	1) 3D: 600 mm 2) Smart Pan: 600 mm 3) Cephalo: 1700 mm
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible
Dose Information		
CT Mode	CTDIw=8.28mGy At FOV Ø 16*9 , 0.2mm Cu filter Irradiation parameters :90kV,10mA, 24s	unknown
Panorama	DAP = 280.8 mGy· cm^2 (Irradiation parameters: 80kV, 10mA, 14s)	unknown
Cephalo	- Scan type, DAP= 48.6 mGy·cm^2 (Irradiation parameters: 80kV, 10mA, 8s)	unknown

7. Determination of Substantial Equivalence

The eco-x Series (eco-x, eco-x-s) is substantially equivalent to the predicate devices 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 eco-x Series is considered substantially equivalent to the predicate devices

8. Non-Clinical Test Summary

The eco-x Series (eco-x, eco-x-s) 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.

A. Thermal, electrical, mechanical safety & Electromagnetic Compatibility

The eco-x 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 IEC 60601-1:2005/AMD1:2012
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014
- Radiation Protection In Diagnostic X-Ray Equipment requirements of IEC 60601-1-3:2008/AMD1:2013
- Dental Extra-Oral X-Ray Equipment requirements of IEC 60601-2-63:2012/AMD1:2017
- Acceptance Tests - Imaging Performance of Dental X-Ray requirements of IEC 61223-3-4:2000

The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31 and the records are available for review.

B. Biocompatibility

A biocompatibility test is not necessary when considering the device's characteristics.

C. Software Validation

The eco-x Series (eco-x, eco-x-s) utilizes original software and OTS software as an image viewer. The eco-x 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: "The content of premarket submissions for software contained in medical devices, on May 11, 2005."

D. 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 and patient dosage meet the criteria under the designated tolerance. Image quality and dose comparison tests showed the substantial equivalence of the eco-x Series to the predicate device.

Furthermore, imaging performance testing was conducted according to IEC 61223-3-4 standard. The test results show that the eco-x Series met all requirements of the standard.

E. 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 submissions of 510(k)'s for Solid State X-ray Imaging Devices". MTF (Modulation Transfer Function) and DQE (Detective Quantum Efficiency) were tested, measured, and compared with the detectors of the predicate device. Although some specifications of the utilized detectors differed from 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. Summary

In conclusion, the conducted tests, as well as all verification and validation activities, demonstrate that the design specifications and technological characteristics of the eco-x 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 eco-x Series is substantially equivalent to the predicate devices.