DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 30, 2016

HDX WILL CORP.
% Mr. Hyung-Suk Oh
General Manager
#105, 201, 202, 203, 204, 38
Osongsaengmyeong 4-ro, Osong-eup Heungdeok-gu
Cheongju-si, Chungcheongbuk-do 28161
REPUBLIC OF KOREA

Re: K160140
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: II
Product Code: OAS
Dated: September 2, 2016
Received: September 6, 2016

Dear Mr. Oh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160140

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 though computer-processed to produce 3D x-ray tomographic images. The DENTRIα series is 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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Chungcheongbuk-do, 28161, Korea, Tel: +82-43-710-7318/ Fax: +82-43-710-7312

510(k) Summary

[As required by 21 CFR 807.92]

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

September 02, 2016

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

- Name of Manufacturer: HDX WILL CORP.
- Address: #105, 201, 202, 203, 204, 38, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea

- Contact Name: Hyung-suk Oh/ General Manager
  - Telephone No.: +82-43-710-7318
  - Fax No.: +82-43-710-7312
  - Email Address: wrcohs@iwillmed.com

- Registration No.: In process

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

Trade Name	DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)
Regulation Name	Computed tomography x-ray system
Classification Panel	Radiology
Classification Regulation	21 CFR 892.1750
Product Code	OAS
Device Class	II

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: K093590
- Applicant: PLANMECA OY
- Regulation Name: Extraoral source x-ray system
- Product Code: MUH
- Device Class: Class II
- Device Name: PLANMECA PROMAX 3D MAX

Predicate device #2

- 510(k) Number: K142247
- Applicant: RAY Co.,Ltd
- Regulation Name: Computed tomography x-ray system
- Product Code: OAS
- Device Class: Class II
- Device Name: RAYSCANα-Expert 3D

There are no significant differences between the DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα) 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 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 are classified as shown below.

DENTRIα: CT Mode + PANORAMA Mode
DENTRI-Cα: CT Mode + PANORAMA Mode + CEPHALO Mode (ONE-SHOT)
DENTRI-Sα: CT Mode + PANORAMA Mode + CEPHALO Mode (SCAN)

2) Description of the image detectors used.

- CT detector

Model	Proposed Device		Predicate Device #1	Predicate Device #2
	DENTRIα, DENTRI-Cα, DENTRI-Sα		PROMAX 3D MAX	RAYSCAN α–Expert3D
Contents	CT detector (option)		3D detector	CT detector
Detector model	Xineos-1313	PaxScan1313DX	Not known	C10900D
Manufacturer	Teledyne DALSA	Varian Medical Systems	Not known	Hamamatsu
Detector type	Flat panel detector	Flat panel detector	Flat panel detector	Flat panel detector
Resolution (pixels)	1,316 x 1,312	1,024 x 1,024	Not known	624 × 624
Pixel size (㎛)	100.1	127.0	127.0	200.0
MTF	57% at 1 LP/mm	55% at 1 LP/mm	Not known	60% at 1 LP/mm
DQE	70% at 0 LP/mm	58% at 1 LP/mm	Not known	23% at 1 LP/mm
Active area (mm)	131 x 131	130 x 130	193 x 242	124.8 x 124.8
A/D Conversion	14 bits	16 bits	Not known	13 bits
FDA 510(k) Number	Not known	Not known	Not known	K122981 (System)

- PANORAMA detector

Model	Proposed Device		Predicate Device #1	Predicate Device #2
	DENTRIα, DENTRI-Cα, DENTRI-Sα		PROMAX 3D MAX	RAYSCAN α–Expert3D
Contents	PANORAMA detector (option)		Smart Pan detector	PANO detector
Detector model	Xineos-1313	PaxScan1313DX	Not known	C10500D
Manufacturer	Teledyne DALSA	Varian Medical Systems	Not known	Hamamatsu
Detector type	Flat panel detector	Flat panel detector	Flat panel detector	Flat panel detector
Resolution (pixels)	1,316 x 1,312	1,024 x 1,024	Not known	60 x 1,512

Model	Proposed Device		Predicate Device #1	Predicate Device #2
	DENTRIα, DENTRI-Cα, DENTRI-Sα		PROMAX 3D MAX	RAYSCAN α–Expert3D
Contents	PANORAMA detector (option)		Smart Pan detector	PANO detector
Pixel size (㎛)	100.1	127.0	127.0	100.0
MTF	57% at 1 LP/mm	55% at 1 LP/mm	Not known	70% at 1 LP/mm
DQE	70% at 0 LP/mm	58% at 1 LP/mm	Not known	50% at 1 LP/mm
Active area (mm)	6 x 131	3.94 x 128.78	13 x 162	6 x 148
A/D Conversion	14 bits	16 bits	Not known	14 bits
FDA 510(k) Number	Not known	Not known	Not known	K122981 (System)

- CEPHALO detector (ONE-SHOT)

Model	Proposed Device	Predicate Device #1	Predicate Device #2
	DENTRI-Cα	PROMAX 3D MAX	RAYSCAN α–Expert3D
Contents	CEPHALO (ONE-SHOT)	Planmeca ProCeph	Ceph (One shot, Large Size) detector
Detector model	FLAATZ 330N	Not known	PaxScan 4336X
Manufacturer	DR Tech	Not known	Varian
Detector type	Flat panel detector	Flat panel detector	Flat panel detector
Resolution (pixels)	2,048 x 1,536	Not known	3,072 x 2,560
Pixel size (㎛)	129.0	139.0	139.0
MTF	83.3% at 2 LP/mm	Not known	54% at 1 LP/mm
DQE	38.5% at 0 LP/mm	Not known	20% at 1 LP/mm
Active area (mm)	193 x 259	302 x 249	427 x 356
A/D Conversion	14 bits	Not known	16 bits
FDA 510(k) Number	Not known	Not known	K121513 (System)

- CEPHALO detector (SCAN)

Model	Proposed Device	Predicate Device #1	Predicate Device #2
	DENTRI-Cα	PROMAX 3D MAX	RAYSCAN α–Expert3D
Contents	CEPHALO (SCAN)	Scanning Ceph	Ceph (Scan) detector
Detector model	Argus-Ceph (DM-20-08K10)	Not known	XID-C24DS
Manufacturer	Teledyne DALSA	Not known	i3System
Detector type	Scanning detector (CCD-TDI)	CCD detector	CdTe (Direct type)
Resolution (pixels)	8160 x 256	Not known	48 x 2400
Pixel size (㎛)	27.0	48.0	100.0
MTF	70% at 1 LP/mm	Not known	75% at 1 LP/mm
DQE	50% at 0 LP/mm	Not known	88% at 1 LP/mm
Active area (mm)	6.9 x 221	6 x 292	4.8 x 240
A/D Conversion	16 bits	Not known	Not known
FDA 510(k) Number	K141130 (System)	Not known	K131695 (System)

Information for detector own 510(K) number or system in which it was cleared 510(k) number.

Contents	Model	Own 510(K) number	System in which it was cleared 510(k) number.
CEPHALO detector (SCAN)	Argus-Ceph (DM-20-08K10)	No	1) System name: ENCOMPASS HF100 2) Manufacturer: Panoramic Corp. 3) 510(K) Number: K141130

The DENTRIα series has been communicated with the Workstation for the transmission of data using Ethernet cable and RS232 Cable. The CBCT system of DENTRIα series has not a wireless option for the transmission of data

3) 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
4. Form of beam output : Gaussian

6. Intended 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 though computer-processed to produce 3D x-ray tomographic images. The DENTRIα series is used by physicians, dentists, and x-ray technologists.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Non-Clinical Test Summary

1) Electrical Safety, Electromagnetic Compatibility and Performance:

The DENTRIα series complies with the electrical safety and electromagnetic compatibility requirements established by the standards AAMI ES60601-1 and IEC 60601-1-2.

Bench testing of the subject devices includes:

- Testing to confirm compliance with the Basic Safety and Essential Performance requirements of AAMI ES60601-1
- Testing to confirm compliance with EMC requirements of IEC 60601-1-2
- Testing to confirm compliance with Radiation Protection In Diagnostic X-Ray Equipment requirements of IEC 60601-1-3
- Testing to confirm compliance with Dental Extra-Oral X-Ray Equipment requirements of IEC 60601-2-63
- Testing to confirm compliance with Acceptance Tests - Imaging Performance Of Dental X-Ray requirements of IEC 61223-3-4

The manufacturing facility is in conformance with the relevant EPRC standards as specified in 21 CFR 1020.30, 31, and 33 and the records are available for review.

2) Software Validation

The DENTRIα series use 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 type of reconstruction is FBP.

Software information is provided in accordance with FDA guidance: "The content of premarket submissions for software contained in medical devices, on May 11, 2005."

3) Biocompatibility

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

4) SSXI 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".

Clinical Test Summary

The clinical images of patients are presented as the clinical data including date and signature by a licensed professional. The report concluded that the images taken with the subject device are of good diagnostic quality.

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

	Proposed Device	Predicate Device #1	Predicate Device #2	SE note
K Number	K160140	K093590	K142247	-
Model	DENTRIα series (DENTRIα, DENTRI-Cα, DENTRI-Sα)	PLANMECA PROMAX 3D MAX	RAYSCANα-Expert 3D	-
Manufacturer	HDX WILL CORP.	PLANMECA OY	RAY Co.,Ltd	-
Intended 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	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	RAYSCAN α–Expert 3D, panoramic x-ray imaging system with cephalostat, is an extraoral source x-ray system, which is intended for dental radiographic examination of the teeth, jaw, and oral structures, specifically	Similar

	Proposed Device	Predicate Device #1	Predicate Device #2	SE note
	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 though computer-processed to produce 3D x-ray tomographic images. The DENTRIα series is used by physicians, dentists, and x-ray technologists.	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.	for panoramic examinations and implantology and for TMJ studies and cephalometry, and it has the capability, using the CBCT technique, to generate dentomaxillofacial 3D images. 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. 2D Image is obtained using the standard narrow beam technique.	
Operation Mode	1) CT 2) Panorama 3) Cephalo ・One shot type ・Scan type	1) 3D 2) Smart Pan 3) Cephalo ・Planmeca ProCeph ・Scanning Ceph	1) CT 2) Panorama 3) Cephalo ・One shot type ・Scan type	Same
X-ray tube assembly				
X-ray tube	OPX/105 (C.E.I. X-ray tube)	Toshiba D-067SB	Not known	-
Focal spot size	0.5 mm	0.6 mm	0.5 mm	Same #2
Target angle	Target angle 5°	Target angle 12°	Target angle 5°	Same #2
Permanent filtration	0.5 mmAl (IEC 60522)	Inherent Filtration At least 0.8 mm Al at 50 kV	Inherent Filtration At least 0.8 mm	Similar
Total filtration of X-ray tube assembly	> 2.5 mmAl	1) 3D: > 2.5 mm Al+ 0.5 mm Cu 2) Smart Pan: > 2.5 mm Al 3) Cephalo: > 2.5 mm Al	> 2.6 mmAl	Similar

	Proposed Device	Predicate Device #1	Predicate Device #2	SE note
Anode material	Tungsten	Tungsten	Tungsten	Same
range of X-ray tube voltage settings	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 %	1) 3D: 60 – 96 kV ± 5 % 2) Smart Pan: 60 – 84 kV ± 5 % 3) Cephalo: 60 – 84 kV ± 5 %	60 - 90kV	Similar
range of X-ray tube current settings	4 - 10mA ± 10 %	1 – 16 mA ± 10 %	4 - 17mA	Similar
range of irradiation time settings	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 %	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 %	1) CT: below 14 s 2) Panorama: below 14 s 3) Cephalo ・One shot type: below 2 s ・Scan type: below 18 s	Similar
Image properties				
Detector type	1) CT: Flat panel 2) Panorama: Flat panel 3) Cephalo ・One shot type: Flat panel ・Scan type: CCD	1) 3D: Flat panel 2) Smart Pan: Flat panel 3) Cephalo: ・Planmeca ProCeph: Flat panel ・Scanning Ceph: CCD	1) CT: Flat panel 2) Panorama: Flat panel 3) Cephalo ・One shot type: Flat panel ・Scan type: CdTe (Direct type)	Similar
Pixel size	1) CT: 100.1 or 127 ㎛ 2) Panorama: 100.1 or 127 ㎛ 3) Cephalo ・One shot type:	1) 3D: 127 ㎛ 2) Smart Pan: 127 ㎛ 3) Cephalo: ・Planmeca	1) CT: 200 ㎛ 2) Panorama: 100 ㎛ 3) Cephalo ・One shot type:	Similar

	Proposed Device	Predicate Device #1	Predicate Device #2	SE note
	129 ㎛ ・Scan type: 27 ㎛	ProCeph: 139 ㎛ ・Scanning Ceph: 48 ㎛	139 ㎛ ・Scan type: 100 ㎛	
Active area (mm)	1) CT: ・131 x 131 mm or ・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	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	1) CT: 124.8 x 124.8 mm 2) Panorama: 6 x 148 mm 3) Cephalo ・One shot type: 427 x 356 mm ・Scan type: 4.8 x 240 mm	Similar
MTF	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	Not known	1) CT: ・60% at 1 LP/mm 2) Panorama: ・70% at 1LP/mm 3) Cephalo ・One shot type: 54% at 1LP/mm ・Scan type: 75% at 1LP/mm	Similar #2
DQE	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	Not known	1) CT: ・23% at 1 LP/mm 2) Panorama: ・50% at 1LP/mm 3) Cephalo ・One shot type: 20% at 1LP/mm ・Scan type: 88 % at 1LP/mm	Similar #2
Geometry				

	Proposed Device	Predicate Device #1	Predicate Device #2	SE note
Source Image Distance (SID)	1) CT: 600 mm 2) Panorama: 560 mm 3) Cephalo: ・One shot type: 1790 mm ・Scan type: 1783 mm	1) 3D: 600 mm 2) Smart Pan: 600 mm 3) Cephalo: 1700 mm	Not known	Similar #1
Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	DICOM 3.0 Format compatible	Same
Dose Information				
CT Mode (Xineos-1313 or PaxScan1313DX)	CTDIw = 11.12mGy At the FOV Ø 10 X 8 90kV, 10mA	CTDIw = 8.34 mGy At the FOV Ø 10 X 8 96kV, 10mA	CTDIw = 10.61 mGy At the FOV Ø 9 X 9 90kV, 10mA	Similar
Panorama (Xineos-1313)	DAP = 198.8 mGy·cm^2 At the 80kV, 10mA, 14s	Not known	DAP = 159.0 mGy·cm2 At the 80kV, 13mA, 14s	Similar #2
Panorama (PaxScan1313DX)	DAP = 119.0 mGy·cm^2 At the 80kV, 10mA, 14s			
Cephalo One shot type	DAP = 26.7 mGy·cm^2 At the 80kV, 10mA, 0.5s	Not known	DAP = 38.4 mGy·cm^2 At the 80kV, 10mA, 0.3s	Similar #2
Cephalo Scan type	DAP = 21.3 mGy·cm^2 At the 80kV, 10mA, 8.2s	Not known	DAP = 65.8 mGy·cm^2 At the 80kV, 10mA, 8.0s	Similar #2

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 predicate device in technological characteristics, output characteristics and operation mode.

The table also provides rationale for a little difference in support of substantial equivalence to the Predicate devices

Justification to Support Substantial Equivalence
Image properties
There is a little difference of image properties including MTF and DQE because the used detectors are different. With respect to the functional aspects, the submitted device is enough to perform each modes. The clinical data clearly shows that the DENTRIα series is effective. The little differences of image properties has no effect for diagnosis of the patients in terms of the safety and effectiveness.
Dose Information
The dose information depends on the technological characteristics of device such as FOV size, filtration of X-ray tube, condition of radiation (kV, mA, time) and Source Image Distance (SID). The DENTRIα series has demonstrated that the data does not exceed 50 % according to requirements of Chapter 203.6.4.5 in IEC 60601-2-63. The submitted device is within the same range at similar settings. The dosage does not affect the display outputs.

There are no significant differences between the DENTRIα series and the predicate device.

When compared to the predicate devices (K093590, K142247), the DENTRIα series in this submission presented the substantial equivalence in terms of:

- Technological characteristics
- Output characteristics
- Operation Mode

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

The DENTRIα series has similar intended use and technical characteristics to the predicate device. Based on those information, we conclude that the DENTRIα series is substantially equivalent to the predicate device and does not raise any new questions regarding safety or effectiveness.