June 9, 2023

Palodex Group OY
℅ Frank Ray
Director Regulatory Affairs
Nahkelantie 160
Tuusula, Etela-Karjala 04300
FINLAND

Re: K230505
Trade/Device Name: Orthopantomograph™ OP 3D LX
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: May 12, 2023
Received: May 12, 2023

Dear Frank Ray:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*
K230505

Device Name
ORTHOPANTOMOGRAPH™ OP 3D LX

Indications for Use *(Describe)*
ORTHOPANTOMOGRAPH™ OP 3D LX is an X-ray device that is intended to be used for imaging of adult and pediatric patients. The device can be configured to take panoramic, cephalometric or 3D images of cranio-maxillofacial complex including the ear, nose and throat (ENT) and airway regions, and cervical spine. The device can be configured to take carpus images.

The device is operated and used by qualified healthcare professionals.

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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Section V – 510(k) Summary
for
ORTHOPANTOMOGRAPH™ OP 3D LX

1. Submitter Information:

Palodex Group Oy
Nahkelantie 160
FI-04300, Tuusula
Finland

Contact Person: Frank Ray
Telephone Number: (+358)10 270 2000
E-mail: frank.ray@envistaco.com

Date Prepared: June 9, 2023

2. Device Name:

- Proprietary Name: ORTHOPANTOMOGRAPH™ OP 3D LX
- Manufacturer: Palodex Group Oy
- Common Name: X-Ray, Tomography, Computed, Dental
- Classification Name: Computed tomography x-ray system
- CFR Number: 21 CFR 892.1750
- Device Class: II
- Product Code: OAS

3. Predicate Device (Primary):

- Proprietary Name: ORTHOPANTOMOGRAPH™ OP 3D (K180947)
- Manufacturer: Palodex Group OY
- Common Name: X-Ray, Tomography, Computed, Dental
- Classification Name: Computed tomography x-ray system
- CFR Number: 21 CFR 892.1750
- Device Class: II
- Product Code: OAS

Predicate Device #2:

- Proprietary Name: Orthopantomograph OP300 (K163423)
- Manufacturer: Palodex Group OY
- Common Name: X-Ray, Tomography, Computed, Dental
- Classification Name: Computed tomography x-ray system
- CFR Number: CFR 892.1750
- Device Class: II
- Product Code: OAS

4. Description of Device:

ORTHOPANTOMOGRAPH™ OP 3D LX manufactured by PaloDEx Group Oy is a panoramic, cephalometric and cone beam CT (CBCT) x-ray device for 2D and 3D imaging of patient's cranio-maxillofacial complex. It can be used to capture 2D and 3D x-ray images from pediatric and adult patients. The Primary Predicate Device ORTHOPANTOMOGRAPH™ OP 3D has already been cleared for panoramic and cone beam CT usage (K180947).

The ORTHOPANTOMOGRAPH™ OP 3D LX is an X-ray device that can be configured to take panoramic, cephalometric or 3D images of craniomaxillofacial complex, and neck areas including the ear, nose and throat (ENT). The device can be configured to take carpus images. The device is operated and used by qualified healthcare professionals. The ORTHOPANTOMOGRAPH™ OP 3D LX is intended to be used for imaging of adult and pediatric patients.

The ORTHOPANTOMOGRAPH™ OP 3D LX is part of digital dental workflow providing image data for diagnosis and treatment planning for the healthcare professionals. X-ray images reveal the targeted craniofacial anatomy, and condition and the position of anatomical structures inside FOV, such as teeth, mandibular joints, and oral and nasal cavities. This helps dentists to prepare for various dental procedures such as implant placement, orthodontics and dental prosthetics, providing possible early diagnosis, which enables early and less invasive treatment.

Per the Guidance for Industry and FDA Staff entitled, "*Bundling Multiple Devices or Multiple Indications in a Single Submission*," dated June 22, 2007, PaloDEx Group Oy is bundling the ORTHOPANTOMOGRAPH™ OP 3D LX models below as they do not differ significantly in purpose, design, materials, energy source, function or any other feature related to substantial equivalence. The device description and intended use are identical for all models listed below. Also the supporting data is relevant to the ORTHOPANTOMOGRAPH™ OP 3D LX as a whole, the bundled device components and accessories are used together during therapeutic procedures, and one review group will be involved.

Table 5.1: ORTHOPANTOMOGRAPH™ OP 3D LX models

Model Type	Model Part Numbers	Description
PCX-1	0.805.5753 (SAP) / 901265-PTU (Oracle)	OP 3D LX (PAN 3D)
PCX-1	0.805.5754 (SAP) / 901266-PTU (Oracle)	OP 3D LX (PAN CEPH 3D

Principle of Operation / Mechanism of Action:

Panoramic imaging is used for acquiring 2D images. In the panoramic mode the rotating unit rotates around patient head and scans the patient with a narrow x-ray beam. Generation of exposure is turned off and turned on during the exposure to produce partial panoramic, bitewing (BW) and TMJ (Temporo Mandibular Joint) images.

Cephalometric imaging is performed by utilizing a second x-ray source. System is using same sensor for all imaging modalities. Both the x-ray source and the rotating unit make a scanning movement to produce either lateral cephalometric or PA image of the patient's head by using a narrow x-ray beam. Patient head is positioned in the ceph

head support. For carpus imaging there is a dedicated carpus holder to be attached to the ceph head support for supporting the object during exposure.

In 3D CBCT mode the rotating unit rotates around patient's head and scans the patient with a rectangular beam, where the beam size is adjusted depending on the selected FOV (Field-of-View) size. Several 2D projection images are recorded during this rotational movement. These 2D images are saved, and based on the data, the 3D data is generated by reconstruction. Once images are reconstructed, they can be viewed in an image viewing software (dental application). The image viewing software is not part of this proposed device.

Accessories:

The Accessories for the ORTHOPANTOMOGRAPH™ OP 3D LX are listed in Table 5.1A below. All Accessories are the same/identical to the cleared Primary Predicate Device ORTHOPANTOMOGRAPH OP 3D (K180947).

Table 5.1A: Accessories

Device / Accessory	Description	Manufacturer
Disposable covers	Intended to serve as a disposable barrier for dental instruments to reduce the risk of cross contamination between dental patients.	Palodex Group Oy
Chin rest	Used with bite block or lip support in standard and pediatric imaging to provide patient support	Palodex Group Oy
Bite block	Used with chin rest in standard and pediatric imaging for dentate patients to provide patient support	Palodex Group Oy
Lip support	Used with chin rest in standard and pediatric imaging for edentulous patients and for TMJ imaging to provide patient support	Palodex Group Oy
Head support	Used to provide patient support	Palodex Group Oy
Carpus holder	Used in carpus imaging to provide patient support	Palodex Group Oy

5. Indications for Use:

ORTHOPANTOMOGRAPH™ OP 3D LX is an X-ray device that is intended to be used for imaging of adult and pediatric patients. The device can be configured to take panoramic, cephalometric or 3D images of cranio-maxillofacial complex including the ear, nose and throat (ENT) and airway regions, and cervical spine. The device can be configured to take carpus images.

The device is operated and used by qualified healthcare professionals.

6. Substantial Equivalence:

- Details of the similarities between subject and predicate devices:

The similarities between Subject Device, ORTHOPANTOMOGRAPH™ OP 3D LX, and the Primary Predicate Device, ORTHOPANTOMOGRAPH™ OP 3D (K180947), are listed in Table 12.1 below for Technological Characteristics and Performance Testing.

The proposed device ORTHOPANTOMOGRAPH™ OP 3D LX shares the similar architectural components and utilize similar X-ray generation as ORTHOPANTOMOGRAPH™ OP 3D (K180947). Both devices utilize cone beam x-ray technology to acquire volumetric data. The Conical x-ray beam rotates around the patient's head and incidents upon the receptor and the system generates volumetric data from the 2D projection images, similarly to the predicate device. Image modes, 3D resolutions, exposure times and 2D imaging programs are identical. The reconstruction of 3D images from 2D image data in the proposed device is made using the same reconstruction techniques as in the predicate device.

Performance testing were conducted on ORTHOPANTOMOGRAPH™ OP 3D LX.
Image quality testing was performed as part of bench testing, and the result indicate that ORTHOPANTOMOGRAPH™ OP 3D LX is substantially equivalent to the predicate devices.

Biocompatibility evaluation was conducted on patient contacting parts and their material and found to be in conformance with ISO 10993-1 for both proposed and the predicate device.

Software on ORTHOPANTOMOGRAPH™ OP 3D LX is designed according to the manufacturer´s software development guidelines complying with IEC 62304. Testing was performed as part of the electrical safety testing.

- Details of the differences between subject and predicate devices:

There are no major differences between the subject device (ORTHOPANTOMOGRAPH™ OP 3D LX) and predicate devices (ORTHOPANTOMOGRAPH™ OP 3D (K180947) and ORTHOPANTOMOGRAPH™ OP300 (K163423)), however there are some minor differences as described below.

Intended Use/Indications of use:
"Ear, nose and throat (ENT) and airway regions, and cervical spine." is not part of the primary predicate intended use/indications of use. Secondary predicate ORTHOPANTOMOGRAPH™ OP300 (K163423) has also "neck area, ear, nose and throat (ENT) regions" included in the intended use/indications of use. Performance testing demonstrates the proposed ORTHOPANTOMOGRAPH™ OP 3D LX and both predicate devices can image the same anatomical areas, that is the dentomaxillofacial complex and neck area which include the airway regions and cervical spine.

As a summary ORTHOPANTOMOGRAPH™ OP 3D LX Indications for Use statement is utilizing more descriptive wording to communicate anatomical structures inside the scanned volume.

X-ray source:
The proposed and the predicate devices utilize the same x-ray tube. The chosen technique factors are slightly different. The small difference in the device´s tube current is due to the proposed device having longer SID requiring a bit larger current for imaging.

Image Detectors:
The proposed device has only one TFT (Thin Film Transistor) sensor capable of capturing all modalities (panoramic, cephalometric and CBCT image data).

Using only one sensor is possible due to the bigger image detector size at the proposed device (Effective detector area 240 x168 mm) compared to the Primary Predicate (Effective detector area 125 x125 mm).

TFT imaging performance is similar to CMOS sensors used with the Predicate device and equivalent clinical performance can be achieved. Measured DQE performance is substantially equivalent to the predicate device.

3D Field of View:
The larger image detector in the proposed device enables bigger field of view options. Field of view options in the proposed device are optimized for clinical needs to achieve intended use of the device.

Pixel size:
The proposed and the primary predicate device have almost identical pixel sizes. 5 µm /10 µm difference in pixel sizes is not significant in clinical practice.

System footprint:
Minor difference in the adjustable height of the device does not impact the safety or effectiveness of the device.

Materials (Patient contacting):
The proposed device uses the same materials for the patient contacting parts with exception for the head support. ORTHOPANTOMOGRAPH™ OP 3D LX uses "Grilamid TR 90+ EMD- 802744 MB Black" also for the head support and "Ultradur B2550 FC+ EMD-802744 MB Black" is not used.

However, these minor differences do not raise new concerns of substantial equivalence. The comparison below (Table 5-2) for the Subject Device and Predicate Devices demonstrates that the Subject device is substantially equivalent to the Primary Predicate with regards to their Indications for use, technology and performance specifications.

Furthermore the subject device does not introduce a fundamentally new scientific technology, and nonclinical performance testing demonstrates that the device is substantially equivalent as the Subject device performs as well as the Primary Predicate device for its intended use.

Device Comparison Table:

Table 5.2: SE Table

Discriptive Information	**Subject Device** ORTHOPANTOMOGRAPH ™ OP 3D LX	**Primary Predicate Device** ORTHOPANTOMOGRAPH ™ OP 3D **(K180947)**	**Predicate Device #2** Orthopantomograph OP300 **(K163423)**	**Comparison**
Regulatory Information				
Manufacturer	Palodex Group OY	Palodex Group OY	Palodex Group OY	Same
Regulation #	21 CFR 892.1750	21 CFR 892.1750	21 CFR 892.1750	Same
Regulation Title	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	Same
Regulation Class	Class II	Class II	Class II	Same
Product Code	OAS	OAS	OAS	Same
Indications for Use/Intended Use				
Indications for Use	ORTHOPANTOMOGRAPH™ OP 3D LX is an X-ray device that is intended to be used for imaging of adult and pediatric patients. The device can be configured to take panoramic, cephalometric or 3D images of cranio-maxillofacial complex including the ear, nose and throat (ENT) and airway regions, and cervical spine. The device can be configured to take carpus images. The device is operated and used by qualified healthcare professionals.	ORTHOPANTOMOGRAPH™ OP 3D is an x-ray device that is intended to be used for imaging of adult and pediatric patients. The device can be configured to take panoramic, cephalometric, or 3D images of the cranio-maxillofacial complex for use in diagnostic support. The device can also be configured to take carpus images. ORTHOPANTOMOGRAPH™ OP 3D must only be used and operated by dentist and other qualified professionals.	ORTHOPANTOMOGRAPH™ OP300 panoramic, cephalometric and cone beam computed tomography x-ray device is intended to image the head and neck areas for diagnostic support. This includes temporomandibular Joints (TMJs) and dentomaxillofacial areas, and with the 13x15 cm field of view (FOV) this additionally includes the ear, nose and throat (ENT) regions. The x-ray device produces conventional 2D x-ray images and x-ray projection images for the reconstruction of a 3D view. The device is operated and used by qualified healthcare professionals.	Same Indication for Use as Primary Predicate and Predicate #2 and expressed through a similar choice of words.
Technological Characteristics				
Imaging modes	Panoramic, TMJ, BW, 3D (CBCT), cephalometric	Panoramic, TMJ, BW, 3D (CBCT), cephalometric	Panoramic, TMJ, 3D(CBCT), cephalometric	Identical to Primary Predicate
X-ray source	3D mode: 95kV Pan mode: 60-90 kV Ceph mode :60-95kV kV accuracy: +/-5kV	3D mode: 95kV Pan mode: 60-90 kV Ceph mode :60-95kV kV accuracy: +/-5kV	3D mode: 90kV Pan mode: 57-90 kV Ceph mode: 60-90 kV kV accuracy: +/-5kV	Similar to Primary Predicate

Discriptive Information	**Subject Device** ORTHOPANTOMOGRAPH ™ OP 3D LX	**Primary Predicate Device** ORTHOPANTOMOGRAPH ™ OP 3D **(K180947)**	**Predicate Device #2** Orthopantomograph OP300 **(K163423)**	**Comparison**
	mA range: 2-16 mA 3D power mode: continuous/pulsed	mA range: 1-16 mA 3D power mode: continuous/pulsed	mA range: 3.2-16 mA 3D power mode: pulsed	
Focal spot	0.5 mm	0.5 mm	0.5mm	Identical to Primary Predicate
Image detector(s)	TFT Flat Panel Detector FXDD-1724RA (Vivix-D 1724R) (2D and 3D)	CMOS Flat Panel CD41M115 (3D) CMOS detector CD51M114/CD52M21X (2D)	CMOS Flat Panel C10900D-05 (3D) CMOS detector C10500D/C10502D (2D)	Similar to Primary Predicate
Image detector scintillator	CsI	CsI	CsI	Same
2D imaging performance – DQE 70kV, RQA5	55% @ 1lp/mm 40% @ 2lp/mm	45% @ 1lp/mm 30% @ 2lp/mm	N/A	Similar to Primary Predicate
2D imaging performance – MTF 70kV, RQA5	60% @ 1lp/mm 30% @ 2lp/mm	60% @ 1lp/mm 30% @ 2lp/mm	N/A	Identical to Primary Predicate
3D imaging technique	Reconstruction from 2D images	Reconstruction from 2D images	Reconstruction from 2D images	Identical to Primary Predicate
3D's Field Of View (FOV)	5 x 5 cm 6 x 9 cm 8 x 8 cm 10 x 10 cm 12 x 15 cm (optional) 15 x 20 cm (optional)	5 x 5 cm 6 x 9 cm 9 x 11 cm 9 x 14 cm (optional)	4 x 6 cm 5 x 5 cm 6.1 x 7.8 cm 7.8 x 7.8 cm 7.8 x 15 cm 13 x 15 cm	Similar to Primary Predicate Similar to Predicate #2 (biggest FOV)
3D's total viewing angle	360º	360º	360º	Identical to Primary Predicate
Pixel size	Flat Panel Detector 95µm (2D) 190 µm (3D)	CMOS PAN & 3D combo flat panel: 3D pixel size: 198 µm pan/ceph pixel size: 99µm	CMOS flat panel for 3D: 200 µm CMOS for panoramic imaging: 100 µm	Similar to Primary Predicate
Voxel size	80–400 µm	80 - 400 µm	85-420 µm	Identical to Primary Predicate
Reconstruction Software	Filtered Back Projection (FBP)	Filtered Back Projection (FBP)	Filtered Back Projection (FBP)	Identical to Primary Predicate

Discriptive Information	**Subject Device** ORTHOPANTOMOGRAPH ™ OP 3D LX	**Primary Predicate Device** ORTHOPANTOMOGRAPH ™ OP 3D **(K180947)**	**Predicate Device #2** Orthopantomograph OP300 **(K163423)**	**Comparison**
3D's effective exposure time	1,7–20 sec	1,7–20 sec	1.2 - 12.6 sec	Identical to Primary Predicate
Ceph exposure time	8.1–10.5 s	8.1–10.5 s	6,5-20s	Identical to Primary Predicate
Patient's Position	Standing and wheelchair	Standing and wheelchair	Standing and wheelchair	Identical to Primary Predicate
System footprint (includes the operator)	H169-244cm x D 124-149cm x 167cm	H167-247cm x D124-149cm x 167 cm	H161-241cm x D1390cm x W97-193 cm	Similar to Primary Predicate
Weight	App. Pan/3D 120 kg Ceph 155 kg	App. Pan/3D 120 kg Ceph 155 kg	App. Pan/3D 200 kg Ceph 240 kg	Identical to Primary Predicate
3D resolution	Low, standard, high, endo	Low, standard, high, endo	LDT, standard, high, endo	Identical to Primary Predicate
2D imaging programs	Adult Pan, Pediatric Pan, TMJ, BW, Segmented	Adult Pan, Pediatric Pan, TMJ, BW, Segmented	Adult Pan, Pediatric Pan, OrthoZone, Orthogonal Pan, Wide Arch Pan TMJ, BW, Carpus	Identical to Primary Predicate
Materials (Patient contacting parts)	Cycoloy C2800-96174 Grivory GC-4H Polycasa PETG Grilamid TR 90+ EMD-802744 MB Black RP450/RP451, FA5224 (CAS 9002-88-4) PLA MP BIO	Cycoloy C2800-96174 Grivory GC-4H Polycasa PETG Grilamid TR 90+ EMD-802744 MB Black RP450/RP451, FA5224 (CAS 9002-88-4) PLA MP BIO Ultradur B2550 FC+ EMD-802744 MB Black	Cycoloy C2800 7T5D066 Grivory GC-4H Tyril 790-38771 SUSTARIN C, BLACK, POM. Silicone 7154MA, Shore 60 STAMSKIN 07421 RED Udel P-1700 CL2611 Altuglas V825T-101	Similar to Primary Predicate
Energy source	Mains AC	Mains AC	Mains AC	Identical to Primary Predicate
Performance Testing				
Usability	Designed and tested for IEC 60601-1-6 and IEC 62366	Designed and tested for IEC 60601-1-6 and IEC 62366	Designed and tested for IEC 60601-1-6	Identical to Primary Predicate

Discriptive Information	**Subject Device** ORTHOPANTOMOGRAPH ™ OP 3D LX	**Primary Predicate Device** ORTHOPANTOMOGRAPH ™ OP 3D **(K180947)**	**Predicate Device #2** Orthopantomograph OP300 **(K163423)**	**Comparison**
Software	Designed and tested for IEC 62304	Designed and tested for IEC 62304	Designed and tested for IEC 62304	Identical to Primary Predicate
Biocompatibility	Biocompatible per ISO 10993-1:2018	Biocompatible per ISO 10993-1:2018	Biocompatible per ISO 10993-1:2018	Identical to Primary Predicate

Non-Clinical Test Data:

Non-Clinical performance bench testing according to international standards for Computed tomography x-ray system has been conducted to determine conformance in regards to:

- IEC 60601-1:2005 / A1:2012 + A2:2020 (Ed. 3.2): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014/A1:2020 (Ed. 4.1) CONSOLIDATED VERSION: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances -Requirements and tests
- IEC 60601-1-3:2008/A1:2013/ A2:2021 (Ed. 2.2): Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 62304:2006/A1:2015 Edition 1.1 CONSOLIDATED VERSION: Medical device software – Software life-cycle processes
- IEC 60601-1-6:2010/A1:2013/ A2:2020 (Ed. 3.2) CONSOLIDATED VERSION: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-63:2012/ A1:2017/A2:2021 (Ed 1.2): Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
- IEC 62366-1:2015/A1:2020 (Ed 1.1) CONSOLIDATED VERSION: Medical devices - Part 1: Application of usability engineering to medical devices
- ISO 10993-1:2018 10993-1 Fifth edition: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 20417:2021 CORRECTED VERSION 2021-12: Medical devices – Information to be supplied by the manufacturer

- ISO 15223-1:2021 (Ed. 4.0): Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements

- IEC 61223-3-7:2021 (Ed. 1.0): Evaluation and routine testing in medical imaging departments - Part 3-7: Acceptance and constancy tests - Imaging performance of X-ray equipment for dental cone beam computed tomography

- IEC 61223-3-4:2000 (Ed.1.0): Evaluation and routine testing in medical imaging departments – Part 3-4: Acceptance tests – Imaging performance of dental X-ray equipment

- IEC 60336:2020/COR1:2022: Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics- test methods only

- ISO 14971:2019 (3rd Edition): Medical devices — Application of risk management to medical devices

FDA Guidance Documents:

The following list of FDA Guidance Documents were utilized in the development of the ORTHOPANTOMOGRAPH™ OP 3D LX.

- Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process", September 4, 2020

- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, December 20, 2019

- Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2, 2014

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

- Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, September 1, 2016

- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, September 14, 2018

- Medical X-Ray Imaging Devices Conformance with IEC Standards, February 21, 2023

- Off-The-Shelf Software Use in Medical Devices, September 27, 2019

- Pediatric Information for X-ray Imaging Device Premarket Notifications, November 28, 2017

Clinical Performance Data:
A clinical image review was performed in support of establishing substantial equivalence.

Conclusion as to Substantial Equivalence:
Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the ORTHOPANTOMOGRAPH™ OP 3D LX is deemed to be substantially equivalent to the predicate device.