DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 31, 2017

PaloDEx Group Oy
% Mr. Eric Schwandt
Regulatory Manager
Nahkelantie 160
Tuusula, FI-04300
FINLAND

Re: K163423
Trade/Device Name: Orthopantomograph OP300
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: July 24, 2017
Received: August 3, 2017

Dear Mr. Schwandt:

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 (DICE) 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 (DICE) 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,

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)*
K163423

Device Name
Orthopantomograph OP300

Indications for Use *(Describe)*
The 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.

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)

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510(k) SUMMARY for **Orthopantomograph OP300**

Submitter Information:

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Contact Person: Eric Schwandt
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Date Prepared: November 17, 2016
Updated: July 21, 2017

Device Name:

Proprietary Name: Orthopantomograph OP300
Common Name: X-ray, Tomography, Computed, Dental
Classification Name: Computed tomography x-ray system
CFR Number: 892.1750
Device Class: II
Product Code: OAS

Predicate Devices:

Proprietary Name: Scanora 3D
510(k) Number K110839
Common Name: X-ray, Tomography, Computed, Dental
Classification Name: Computed tomography x-ray system
CFR Number: 892.1750
Device Class: II
Product Code: OAS

Proprietary Name: Orthopantomograph OP300
510(k) Number K133544
Common Name: X-ray, Tomography, Computed, Dental
Classification Name: Computed tomography x-ray system
CFR Number: 892.1750
Device Class: II
Product Code: OAS

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Description of Device

Orthopantomograph OP300 x-ray unit is a software controlled diagnostic dental X-ray equipment for producing panoramic, cephalometric and 3D images of the dentomaxillofacial complex, ENT and airway regions of the head and neck. The Orthopantomograph OP300 is available in different configurations (panoramic, cephalometric, 3D) with different 3D Field of View configurations (6X4 cm, 6X8 cm, 5X5 cm, 8X8 cm, 8X15 cm, and 13X15 cm). The components of the device include column, carriage, rotating unit (containing tube head, sensors and collimator), top-level hanger, patient head support, software for image reconstruction, and an optional software package for image reviewing. The proprietary name of the optional image reviewing software is CLINIVIEW.

Cone Beam Volumetric Tomography is a medical imaging technique that uses X-rays to obtain cross-sectional images of the head or neck. The proposed device utilizes cone beam X-ray technology, which generates conical x-ray beams that rotate around the patient's head and incident upon the receptor that generate sufficiently contrasted images. Quality of the images depends on the level and amount of X-ray energy delivered to the tissue. When interpreted by a trained physician, these images provide useful diagnostic information.

Indications for Use:

	Proposed Device Orthopantomograph OP300	**Predicate Device** Scanora 3D (K110839)	**Predicate Device** Orthopantomograph OP300 (K133544)
Indications for use	The 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.	Scanora 3D is a Cone Beam 3D x-ray system for imaging the head and neck areas, including the ENT and dentomaxillofacial areas, for use in diagnostic support. Dedicated panoramic imaging is an option. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by qualified healthcare professionals.	The OP300 dental panoramic, cephalometric and cone beam computed tomography x-ray device is intended for dental radiographic examination of teeth, jaw and TMJ areas by producing conventional 2D x-ray images as well as x-ray projection images of an examined volume for the reconstruction of a 3D view. The device is operated and used by qualified healthcare professionals.

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Technological Characteristics Comparison

	Proposed Device Orthopantomograph OP300		**Predicate Device** Scanora 3D (K110839)		**Predicate Device** Orthopantomograph OP300 (K133544)	
Imaging modes	Panoramic, Cephalometric, TMJ 3D		Panoramic TMJ 3D		Panoramic, Cephalometric TMJ 3D	
x-ray source	3D mode: 90kV Pan mode: 57-90 kV Ceph mode: 60-90 kV kV accuracy: +/-5kV mA range: 3.2-16 mA 3D power mode: pulsed		3D mode: 85 kV Pan mode: 60-81 kV kV accuracy:+/-5 kV mA range: 1 - 8 mA Power mode: pulsed		3D mode: 90kV Pan mode: 57-90 kV Ceph mode: 60-90 kV kV accuracy: +/-5kV mA range: 3.2-16 mA 3D power mode: pulsed	
Focal spot	0.5mm		0.5 mm		0.5mm	
Image detector(s)	CMOS Flat Panel + CMOS for pan/ceph imaging		CMOS Flat Panel + CCD for panoramic imaging		CMOS Flat Panel + CMOS for pan/ceph imaging	
3D imaging technique	Reconstruction from 2D images		Reconstruction from 2D images		Reconstruction from 2D images	
3D's Field Of View	40 x 60 mm 50 x 50 mm 61 x 78 mm 78 x 78 mm 78 x 150 mm 130 x 150 mm		50 x 50 mm 60 x 60 mm 75 x 100 mm 75 x 145 mm 130 x 145 mm		40 x 60 mm 50 x 50 mm 61 x 78 mm 78 x 78 mm 78 x 150 mm 130 x 150 mm	
Available 3D Programs	Field of View	Resolution	Field of View	Resolution	Field of View	Resolution
	40 x 60 mm 50 x 50 mm	Low Dose, Standard, High, Endo	50 x 50 mm 60 x 60 mm 75 x 100 mm 75 x 145 mm 130 x 145 mm	Standard, High	40 x 60 mm 50 x 50 mm	Low Dose, Standard, High, Endo
	61 x 78 mm 78 x 78 mm 78 x 150 mm 130 x 150 mm	Low Dose, Standard, High			61 x 78 mm 78 x 78 mm 78 x 150 mm 130 x 150 mm	Low Dose, Standard, High
3D's total viewing angle	212 degrees		360 degrees		200 degrees	
Pixel size	CMOS flat panel for 3D: 200 µm CMOS for panoramic imaging: 100 µm		CMOS Flat panel for 3D: 200 µm CCD for panoramic imaging: 96 µm		CMOS flat panel for 3D: 200 µm CMOS for panoramic imaging: 100 µm	
Voxel size	85-420 µm		133-350 µm		85-420 µm	

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Recontruction technique	Filtered Back Projection (FBP) or Algebraic Reconstruction Technique (ART)	Filtered Back Projection (FBP) or Algebraic Reconstruction Technique (ART)	Filtered Back Projection (FBP) or Algebraic Reconstruction Technique (ART)
3D's effective exposure time	1.2 - 12.6 sec	2.25 - 6 sec	1.2 - 12.5 sec
3D reconstruction time	1-3 min	1 - 5 min	1-3 min
Software Version	OP300 Firmware: 1.28 OP300 GUI: 1.9	Not Known	OP300 Firmware: 1.21 OP300 GUI: 1.9
Patient's position	Standing and wheelchair	Sitting	Standing and wheelchair
System footprint	H161-241cm x D1390cm x W97-193 cm	H 196 cm D 110 cm W 154 cm	H161-241cm x D1390cm x W97-193 cm

The proposed Orthopantomograph OP300 also shares the same architectural components and principle of operation as the predicate device Scanora 3D (K110839) including:

a. An X-ray source on a motorized rotating unit
b. Collimation of X-ray
c. 2D and 3D image detection
d. Image reconstruction techniques
e. Interfaces to 2D and 3D (3rd party) image acquisition software

The technical characteristics of the proposed device and predicate devices, including imaging technology, available Field of Views, technical resolution and other basic technological characteristics are substantially equivalent. Differences in technical characteristics are so small that they do not have any effect on the device performance in practice. As evidenced through the design verification and validation, the proposed Orthopantomograph OP300 can produce 3D images of the maxillofacial (including ENT and airway) areas and the images are of equivalent diagnostic quality as the images with the predicate device Scanora 3D. The slightly bigger Field-of-View of the proposed Orthopantomograph OP300 compared to predicate device Scanora 3D does not negatively affect imaging of the intended anatomical structures and does not affect substantial equivalence of the device.

Non-Clinical Performance Data

As part of the design control activities, the Orthopantomograph OP300 device has successfully passed design verification and validation. The substantial equivalence of the proposed Orthopantomograph OP300 for the proposed indications for use has been substantiated via an image comparison study of predicate device Scanora 3D and proposed device Orthopantomograph OP300 images from ENT, airway and maxillofacial areas.

Biocompatibility evaluation was conducted on patient contacting accessory parts and their material and found to be in conformance with ISO 10993-5 and ISO 10993-10.

EMC and Electrical Safety testing were performed by 3rd party test house and found to meet all the requirements in standards IEC 60601-1: 2005, IEC 60601-1-6:2013, IEC 62366:2014, IEC 60601-2-63:2012, IEC 60601-2-28:2010, IEC 60601-1-2:2007, and IEC 60601-1-3:2013.

Clinical Performance Data:

Clinical images acquired using Orthopantomograph OP300 were reviewed by qualified clinicians to be of acceptable quality for the proposed indications for use.

Conclusion as to Substantial Equivalence

The indications for use for the proposed device Orthopantomograph OP300 include imaging of head and neck, and ENT. The proposed device has been verified and validated to satisfy the requirements derived from the proposed indications for use. Indications for use of proposed device Orthopantomograph OP300 including imaging of head and neck, and ENT are similar to predicate device Scanora 3D (K110839). As evidenced through the design verification and validation, the proposed Orthopantomograph OP300 can produce 3D images of the maxillofacial (including ENT) areas and the images are of equivalent diagnostic quality as the images with the predicate device Scanora 3D.

Based on the comparison of intended use, principles of operation, technological characteristics, non-clinical and clinical performance data, the minor differences between the proposed Orthopantomograph OP300 with expanded indications for use, and the predicate devices, Scanora 3D (K110839) and Orthopantomograph OP300 (K133544), do not raise new concerns regarding safety and effectiveness for the proposed indications of use. We conclude that the proposed device Orthopantomograph OP300 is substantially equivalent to the predicate devices.