



Food and Drug Administration
10903 New Hampshire Avenue
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PaloDEX Group Oy
% Terho Turkumaki
QA&RA Manager
Nahkelantie 160
FI-04300 Tuusula
FINLAND

April 7, 2017

Re: K170813
Trade/Device Name: ORTHOPANTOMOGRAPH™ OP 3D
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: March 10, 2017
Received: March 17, 2017

Dear Terho Turkumaki:

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

Indications for Use

510(k) Number (if known)
K170813

Device Name
ORTHOPANTOMOGRAPH™ OP 3D

Indications for Use (Describe)

ORTHOPANTOMOGRAPH™ OP 3D is an x-ray device to take panoramic and 3D images of the cranio-maxillofacial complex for use in diagnostic support.

ORTHOPANTOMOGRAPH™ OP 3D must only be used and operated by dentist and other qualified 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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510(k) SUMMARY for **ORTHOPANTOMOGRAPH™ OP 3D**

Submitter Information:

Palodex Group Oy
Nahkelantie 160
FI-04300 Tuusula
Finland

Contact Person: Terho Turkumäki
Telephone Number: +358 10 270 2000
Fax Number: +358 50 320 9113

Date Prepared: March 10, 2017

Device Name:

Proprietary Name: ORTHOPANTOMOGRAPH™ OP 3D
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 Device:

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

Description of Device

ORTHOPANTOMOGRAPH™ OP 3D x-ray unit is a software controlled diagnostic dental X-ray equipment for producing panoramic and 3D images of the cranio-dentomaxillofacial complex of patient head. The ORTHOPANTOMOGRAPH™ OP 3D has panoramic programs (adult, child, TMJ, BW and partial) and 3D (CBCT) programs with different 3D Field of View configurations. The components of the device include column, carriage, rotating unit (containing tube head, sensors and collimator), upper shelf, patient head support and driver software including image reconstruction. Workstation software for viewing the images is not included in this submission.

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.

The following guidances were followed when preparing this 510k submission:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005
- Guidance for Industry and FDA Staff: Premarket Assessment of Pediatric Medical Devices, March 24, 2014
- Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, September 1, 2016
- Guidance for Industry and Food and Drug Administration Staff: Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, July 11, 2016.
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, September 9, 1999
- Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, October 2, 2014”
- FDA Guidance “Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a Risk management process”.

Description of Substantial Equivalence

Concept		Proposed device (ORTHOPANTOMOGRAPH™ OP 3D)	Predicate device (ORTHOPANTOMOGRAPH™ OP300, K133544)
1.	Indications for Use/ Intended Use	ORTHOPANTOMOGRAPH™ OP 3D is an x-ray device to take panoramic and 3D images of the cranio-maxillofacial complex for use in diagnostic support. ORTHOPANTOMOGRAPH™ OP 3D must only be used and operated by dentist and other qualified 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.
2.	Imaging modes	Panoramic, TMJ, 3D (CBCT)	Panoramic, TMJ, 3D (CBCT), Cephalometric (optional)
3.	Focal spot	0.5mm	0.5mm
4.	Image detector(s)	CMOS Flat Panel	CMOS Flat Panel +CMOS detector (Pan/ceph)
5.	3D imaging technique	Reconstruction from 2D images	Reconstruction from 2D images
6.	3D's Field Of View	5 x 5 6 x 9 9 x 11 9 x 14 (optional)	5x5 6x8 8x8 8x15 13x15 (optional)
7.	3D's total viewing angle	360	360

8.	3D's effective exposure time	1.7 - 20 sec	1.2 - 12.5
9.	3D Reconstruction Time	1-3 min	1-3 min
10.	Patient's Position	Standing and wheelchair	Standing and wheelchair
11.	System footprint (includes the operator)	H167-247cm x D77-100cm x 130 cm	H161-241cm x D139cm x W97-193 cm
12.	Weight	App. 100 kg	App. Pan/3D 205 kg Ceph 240 kg
13	Classification	OAS	OAS
14	3D resolution	Low , standard, high, endo	Low , standard, high, endo
15	2D imaging programs	Adult Pan, Child Pan, TMJ, BW, Partial Pan	Adult Pan, Child Pan, TMJ, BW, Partial Pan
16	CMOS flat panel size	147.3mm x 113.7 mm (1488x1148 pixels)	124.8mm x 124.8mm (1248x1248 pixels)
17	CMOS flat panel pixel size	99um x 99um	100um x 100um
18	System MTF @10%, FOV 5x5 High Res	2.2 lp/mm @125µm voxel	2.25 lp/mm @125µm voxel

Indications for Use

ORTHOPANTOMOGRAPH™ OP 3D is an x-ray device to take panoramic and 3D images of the cranio-maxillofacial complex for use in diagnostic support.

ORTHOPANTOMOGRAPH™ OP 3D must only be used and operated by dentist and other qualified professionals.

The proposed ORTHOPANTOMOGRAPH™ OP 3D has similar Intended Use/ Indications for Use as the predicate device ORTHOPANTOMOGRAPH™ OP300. Difference in Intended Use statements is due to the different imaging modes available. The proposed ORTHOPANTOMOGRAPH OP 3D does not have cephalometric imaging. Cranio-maxillofacial complex encompasses the same anatomy than in the predicate device i.e teeth, jaw and TMJ areas of head.

Principle of Operation

The proposed ORTHOPANTOMOGRAPH™ OP 3D shares similar architectural components and principle of operation as the predicate device ORTHOPANTOMOGRAPH™ OP300. Both devices utilize cone beam x-ray technology to acquire volumetric data, which generates conical x-ray beams that rotate around the patient's head and incident upon the receptor that generate sufficiently contrasted images similar to the predicate devices. 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. Additionally the interfaces to 2D/3D image viewing software are similar. There is no substantial difference in the functionality for the data acquisition, data/image display nor integration with 2D/3D imaging software of ORTHOPANTOMOGRAPH™ OP 3D, when compared to the predicate device. The proposed and the predicate device utilize the similar format for interfacing with the 2D and/or 3D imaging software.

Technological Characteristics

The technical characteristics of the proposed device and predicate device, including imaging technology, available Field of Views, technical resolution and other basic technological characteristics are substantially equivalent to the predicate device ORTHOPANTOMOGRAPH™ OP300. The proposed ORTHOPANTOMOGRAPH™ OP 3D can produce 2D and 3D images of the cranio-maxillofacial areas of equivalent diagnostic quality as the images with the predicate device ORTHOPANTOMOGRAPH OP300 (K133544). Differences in technical characteristics are small and the device performance is equivalent as evidenced through verification and validation testing.

Non-Clinical Performance Data

As part of the design control activities, the ORTHOPANTOMOGRAPH™ OP 3D device has successfully passed internal design verification and validation.

Electrical, mechanical, safety and performance testing according to standards IEC 60601-1: 2005, IEC 60601-1-6:2013, IEC 62366:2014, IEC 60601-2-63:2012, IEC 60601-2-28:2010, and IEC 60601-1-3:2007 were performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2:2014. Testing was completed by 3rd party test house, and the proposed ORTHOPANTOMOGRAPH™ OP 3D has passed all tests.

Biocompatibility evaluation was conducted on patient contacting accessory parts and their material and found to be in conformance with ISO 10993-1.

Software for ORTHOPANTOMOGRAPH™ OP 3D has been categorized as Moderate Level of Concern and documented according to *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

Bench test images acquired using ORTHOPANTOMOGRAPH OP™ 3D was reviewed by qualified clinicians to be of acceptable quality for the proposed Intended Use.

Clinical Performance Data

No clinical images were utilized for this submission. Clinical data was not needed to support substantial equivalence.

Conclusion as to Substantial Equivalence

There are no significant differences between the proposed ORTHOPANTOMOGRAPH™ OP 3D and predicate ORTHOPANTOMOGRAPH™ OP300 (K133544). Minor differences have been shown not to affect the substantial equivalence of the device.

The proposed device does not introduce a fundamentally new scientific technology and the non-clinical tests demonstrate that the device is substantially equivalent with regards to safety and effectiveness. All internal verification and validation has been completed successfully.

In summary, the proposed ORTHOPANTOMOGRAPH™ OP 3D device is substantially equivalent to the predicate ORTHOPANTOMOGRAPH™ OP300 device.