K122018

Attachment 7

510(k) Summary

DEC 10 2012

Date: November 2, 2012

Manufacturer:
PaloDEx Group Oy
Nahkelantie 160
04300 Tuusula, Finland

Tel: +358 10 270 2000
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Contact person: Mr. Matti Tulikoura, Tel +358 400 609 507

Trade Name:
OP300

Common Name:
Dental panoramic, cephalometric and cone beam computed tomography x-ray device

Classification Name:
Computed tomography x-ray system (21 CFR § 892.1750, product code OAS)

Description:
The Orthopantomograph OP300 is an extraoral source, software-controlled dental x-ray device which produces conventional digital 2D panoramic, cephalometric and TMJ x-ray images as well as digital x-ray projection images taken during cone beam rotations around a patient's head. The projection images are reconstructed to be viewed in 3D by a 3D viewing software.

Intended Use:
The unit must only be used and operated by dentist and other qualified professionals. The unit must only be used to take panoramic, cephalometric and 3D images of the dento-maxillofacial complex of the human skull. It must not be used to take images of any other part of the human body.

Summary of Technological Characteristics:
OP300 is substantially equivalent in design, composition and function to the current OP300 unit.

Concept		OP300 (Modified)	OP300 [K093683]
1.	Indications for Use	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.	Same
2.	Imaging modes	Panoramic, Cephalometric, TMJ, 3D	Same
3.	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: 90kV Pan mode: 57-90 kV Ceph mode: 60-90 kV kV accuracy: +/-5kV mA range: 2-16 mA 3D power mode: pulsed/continuous
4.	Focal spot	0.5mm	Same
5.	Image detector(s)	CMOS Flat Panel + CMOS for pan/ceph imaging	Same
6.	3D imaging technique	Reconstruction from 2D images	Same
7.	3D's Field Of View	61 x 41 mm 61 x 78 mm	Same
8.	3D's total viewing angle	200 degrees	Same
9.	Pixel size	CMOS flat panel for 3D: 200 µm CMOS for panoramic imaging: 100 µm	Same
10.	Voxel size	80-350 µm	Same
11.	Reconstruction Software	Filtered Back Projection (FBP) or Algebraic Reconstruction Technique (ART)	Algebraic Reconstruction Technique (ART)
12.	3D's effective exposure time	2.3 - 12.5 sec	2 - 20 sec
13.	3D Reconstruction Time	1-3 min	Same
14.	Patient's Position	Standing and wheelchair	Same
15.	System footprint	H161-241cm x D1390cm x W97-193 cm	Same
16.	Weight	Pan/3D 205 kg Ceph 250 kg	Same

Non-clinical Test Data:
Preference study as an image quality comparison between OP300 and the predicate device was performed. Same patient data was used for the reconstructions and the images were evaluated by internal reviewers and external dental professionals. Validations have been performed successfully to ensure the safety and effectiveness of the OP300 system.

Clinical Test Data:
Clinical testing has not been conducted on OP300 device because CBCT imaging technique and FBP algorithm are widely used. Only a preference study was conducted.

Conclusion:
Based upon the similar technological/performance characteristics to the predicate device [OP300, K093683] and the successful validation of the OP300 software, the clinical performance of the OP300 is deemed to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 10, 2012

PaloDEx Group OY
C/O Mr. Matti Tulikoura
Regulatory Manager
Nahkelantie 160
TUUSULA 04300
FINLAND

Re: K122018
Trade/Device Name: OP300
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: November 5, 2012
Received: November 7, 2012

Dear Mr. Tulikoura:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Janine M. Morris -S

Janine M. Morris
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): K122018

Device Name: OP300

Indications for Use:

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.
Prescription

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
2012.12.10 12:34:35 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) **K122018**