September 12, 2024

Palodex Group Oy
% Riika Sarviaho
Regulatory Affairs Specialist
Nahkelantie 160
Tuusula, 04300
FINLAND

Re: K241249
Trade/Device Name: Orthopantomograph™ OP 3D LX (PAN 3D);
Orthopantomograph™ OP 3D LX (PAN CEPH 3D)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: May 3, 2024
Received: August 13, 2024

Dear Riika Sarviaho:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
Diagnostoc X-Ray Systems Team
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241249

Device Name

Orthopantomograph™ OP 3D LX (PAN 3D);
Orthopantomograph™ OP 3D LX (PAN CEPH 3D)

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K241249

510(k) Summary

Prepared on: 2024-08-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Palodex Group Oy
Applicant Address	Nahkelantie 160 Tuusula 04300 Finland
Applicant Contact Telephone	+358505727161
Applicant Contact	Dr. Riika Sarviaho
Applicant Contact Email	riika.sarviaho@envistaco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Orthopantomograph™ OP 3D LX (PAN 3D); Orthopantomograph™ OP 3D LX (PAN CEPH 3D)
Common Name	Computed tomography x-ray system
Classification Name	Computed tomography x-ray system
Regulation Number	892.1750
Product Code(s)	OAS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230505	Orthopantomograph™ OP 3D LX	OAS

Device Description Summary

21 CFR 807.92(a)(4)

ORTHOPANTOMOGRAPH™ OP 3D LX is a digital panoramic, cephalometric and cone beam computed tomography (CBCT) x-ray device. OP 3D LX is used for imaging of the craniomaxillofacial complex and neck areas including the ear, nose and throat (ENT) for diagnostic and treatment planning purposes.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indications for Use is identical to the Indications for Use of the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

This section provides the substantial equivalence rationale for ORTHOPANTOMOGRAPH™ OP 3D LX, and the Primary Predicate Device, ORTHOPANTOMOGRAPH™ OP 3D LX (K230505) with regards to Indications for Use, Technology, and Performance Testing. As described in this section, the differences between the subject device and the predicate do not raise different questions of substantial equivalence.

Details of the similarities between subject and predicate devices:

The Subject Device shares the same architectural components and utilizes the same X-ray generation as the Predicate Device. Both devices utilize cone beam x-ray technology to acquire volumetric data. Both the Subject Device and the Predicate Device have the same image modes, X-ray source, focal spot, image detectors, image detector scintillator, 2D image performance – DQE / MTF 70kV RAQ5, 3D image technique, 3D field of view, 3D total viewing angle, pixel size, voxel size, reconstruction software, 3D's effective exposure time, Ceph exposure time, Patient position, system footprint, 3D resolution, 2D image programs, and material patient contacting components.

Details of the differences between subject and predicate devices:

There are no major differences between the Subject Device and the Predicate Device. There is one minor difference, the Automatic Exposure Control (Automatic Dose Control) between the Subject Device and the Predicate Device. The Automatic Exposure Control (Automatic Dose Control) is identical to the Predicate #2 device as the Subject Device is available in standard/child panoramic and in all 3D imaging programs as "ADC" feature.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical performance bench testing according to international standards (and FDA recognized consensus standards) for Computed tomography x-ray system has been conducted to determine conformance in regard 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) CONSOLIDATED VERSION: 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 Fifth edition: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 20417:2021 (First edition) 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 (Ed. 5.0): 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
- IEC 81001-5-1:2021 (Ed 1.0): Health software and health IT systems safety, effectiveness and security

The following list of FDA Guidance Documents has been 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 2023
- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions, December 2019
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, September 2023

• Content of Premarket Submissions for Device Software Functions, June 2023
• Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, September 2016
• Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, September 2018
• Medical X-Ray Imaging Devices Conformance with IEC Standards, February 2023.
• Electromagnetic Compatibility (EMC) of Medical Devices, June 2022
• Off-The-Shelf Software Use in Medical Devices, August 2023
• Pediatric Information for X-ray Imaging Device Premarket Notifications, November 2017

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Clinical testing has not been conducted on this product.

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.