July 23, 2026

Hefei Meyer Optoelectronic Technology, Inc.
% Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Rm. 1308, Baohua International Plz.,
West Guangzhong Rd. 555, Jingan District
SHANGHAI, CHINA

Re: K261748
Trade/Device Name: Dental Cone-beam Computed Tomography (mDX-15P Series)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: May 27, 2026
Received: May 28, 2026

Dear Kyra Kang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261748

Please provide the device trade name(s).

Dental Cone-beam Computed Tomography (mDX-15P Series)

Please provide your Indications for Use below.

The equipment is intended to produce two-dimensional (2D) or three-dimensional (3D) images of the human dental, maxillofacial regions and/or skull as diagnostic support for adult and pediatric patients.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K261748

510(k) Summary

I. Submitter

Hefei Meyer Optoelectronic Technology Inc.
No.668 Wangjiang West Road, High & New Tech. Industry Development Zone, 230088
Hefei, PEOPLE’S REPUBLIC OF CHINA
Contact person: Mr. Zixuan Zhao
Position: RA manager
Tel.: +86-18756559593
E-mail: zhaozixuan@meyerop.com

Preparation date: May 14, 2026

Submission Correspondent
Ms. Kyra Kang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
E-mail: kyra.kang@landlink-health.com

II. Proposed Device

Device Trade Name:	Dental Cone-beam Computed Tomography (mDX-15P Series)
Common name:	Computed tomography x-ray system
Regulation Number:	21 CFR 892.1750
Regulatory Class:	Class II
Product code:	OAS
Review Panel:	Radiology

III. Predicate Devices

510(k) Number:	K230985
Trade name:	Planmeca Viso
Common name:	Computed tomography x-ray system.
Classification:	Class II
Product Code:	OAS
Manufacturer	PLANMECA OY

IV. Device description

The device is an advanced digital X-ray imaging unit that producing high quality digital images of dentitionTMJ and skull.

The device uses cone beam computed tomography (CBCT) to produce three-dimensional (3D)radiographic images of the maxilofacial, TMJ and ENT anatomies. The device can also producetwo-dimensional (2D) panoramic (PANO) images with the tomosynthesis method as well as optionalcephalometric (CEPH) images and carpus images with conventional 2D radiography.

The device includes the following models:

- mDX-15Pro-K10
- mDX-15Pro-Y30
- mDX-15Pro-B50
- mDX-15Plus-Y50S

V. Indications for use

The equipment is intended to produce two-dimensional (2D) or three-dimensional (3D) images of the human dental, maxillofacial regions and/or skull as diagnostic support for adult and pediatric patients.

VI. Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate devices are listed in below table

Table 5.2-1 General Comparison

Characteristics	**Proposed device**	**Predicate device (K230985)**	**Discussion**
Trade name	Dental Cone-beam Computed Tomography mDX-15P Series	Dental Computed Tomography X-ray System	/
Classification Name	Computed tomography x-ray system	Computed tomography x-ray system	Same
Product Code	OAS	OAS	Same
Regulation Number	21 CFR 892.1750	21 CFR 892.1750	Same

Indications for use	The equipment is intended to produce two-dimensional (2D) or three-dimensional (3D) images of the human dental, maxillofacial regions and/or skull as diagnostic support for adult and pediatric patients.	Planmeca Viso is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital x-ray images as well as three-dimensional (3D) optical images of the dentomaxillo-facial, cervical spine and ENT (Ear, Nose, and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients	Same
Device Structure	The product consists of X-ray tube assembly, X-ray detector (for CBCT/PANO), X-ray detector (for CEPH/Carpus), column, touch control panel, exposure switch, exposure control box, chin cup, chin support, temple support, nasion support, ear support, TMJ nose support, handle, bite block, workstation, and software (Work Terminal, Data Center, Image Processing).	The product consists of X-ray unit, sensor with digital cameras, patient supports, patient handle, touch screen, moving column, stationary column, 3D reconstruction PC, Planmeca Romexis program, Ethernet switch.	Similar
Power supply	100 ~ 240 VAC 50 / 60 Hz	AC 100-220V 50/60Hz, 230-240V, 50Hz	Analysis 1
Patient population	pediatric and adult patients	pediatric and adult patients	Same
Clinical conditions	The X-ray images can be used for the examination of dental, maxillofacial and/or skull anatomy. The 3D images from CBCT shall only be used as an	This X-ray unit is intended to be used in a professional healthcare environment such as dental offices, clinics and similar environments.	Same

		imaging technique where conventional radiography failed to support diagnosis			
Dimenson		1320 (L) × 1818 (W) × 1640-2340 (H) (mm)		1540 (L) × 2160 (W) × 2340 (H) (mm)	Similar
Tube voltage		60 – 100 kV		60-120kV	Analysis 2
Tube current		2-10mA		2-16mA	Analysis 3
X-ray generator rated output power		1kW		1.6kW	Analysis 4
Focus nominal value		0.5 mm		0.5 mm	Same
Voxel size（mm）		0.07mm, 0.08mm, 0.20mm, 0.25mm		0.6-0.075	Same
SID（Source Image Distance）		mDX-15Plus-Y50S	CBCT/PANO：660 mm CEPH：1700 mm	CT photography: 700mm	Analysis 5
		mDX-15Pro-B50 mDX-15Pro-K10 mDX-15Pro-Y30	CBCT/PANO：565 mm CEPH：1700 mm	Panorama photography: 700mm	
				Cephalometric photography: 1700mm	
Active area&Pixel size	CT	mDX-15Pro-K10: 151*201mm, 100um mDX-15Pro-Y30: 179.2*179.2mm, 100um mDX-15Pro-B50: 157×159.4mm, 120um mDX-15Plus-Y50S: 204.8cm×256mm, 100um		247.7*301.1mm，139um	Analysis 6
	PANO	mDX-15Pro-K10: 11*169 mm, 100um		8.896/17.792*166.8mm，139um	

<table>
<tr><td></td><td></td><td>mDX-15Pro-Y30:
11*169 mm, 100um

mDX-15Pro-B50:
11*159 mm, 120um

mDX-15Plus-Y50S:
11*169 mm, 100um</td><td></td><td></td></tr>
<tr><td></td><td>CE
PH</td><td>mDX-15Pro-K10:
7.2*233.1mm, 100um

mDX-15Pro-Y30:
6.8cm*225.2 mm, 100um

mDX-15Pro-B50:
6*223.2 mm, 100um

mDX-15Plus-Y50S:
300*250 mm, 125um</td><td>301.82*248.9mm，131um</td><td></td></tr>
<tr><td>FOV</td><td colspan="2"><table>
<tr><th>Scan Model</th><th>mDX-15Pro-K10</th><th>mDX-15Pro-Y30</th><th>mDX-15Pro-B50</th><th>mDX-15Plus-Y50S</th></tr>
<tr><td>Skull Scan</td><td>not exist</td><td>not exist</td><td>not exist</td><td>22 × 23*</td></tr>
<tr><td>Maxillofacial Scan</td><td>16 × 18*</td><td>18 × 18*</td><td>17 × 17*</td><td>22 × 16</td></tr>
<tr><td>Dentition Scan</td><td>16 × 12</td><td>18 × 11</td><td>17 × 10</td><td>18 × 11</td></tr>
<tr><td>Dual Arch Scan</td><td>10 × 10</td><td>11 × 11</td><td>10 × 10</td><td>11 × 11</td></tr>
<tr><td>Single Arch Scan</td><td>10 × 6</td><td>10 × 6</td><td>10 × 6</td><td>10 × 6</td></tr>
<tr><td>Teeth Scan</td><td>5 × 8</td><td>5 × 8</td><td>5 × 8</td><td>5 × 8</td></tr>
</table></td><td>26*30，16*16，14*10，
10*10，5*5</td><td>Analysis 7</td></tr>
</table>

		<table><tr><td>Endo Scan</td><td>4 × 4*</td><td>4 × 4*</td><td>4 × 4*</td><td>4 × 4*</td></tr><tr><td>PANO</td><td>20 × 11</td><td>20 × 11</td><td>20 × 11</td><td>20 × 11</td></tr><tr><td>CEPH</td><td>23 × 19</td><td>23 × 19</td><td>23 × 19</td><td>26 × 21</td></tr></table>* The scans with this mark are optional.		
Scan time		0.8 – 16 s (depending on scan mode)	Max 36s	Analysis 8
Software	Compatibility	Dicom 3.0 format compatible	Dicom 3.0 format compatible	Similar
	Name	Workstation System Software, Control System Software	Planmeca Romexis	
	Function	The storage and management of all data including patient information and images. The operator to add patients, acquire images, and analyze images daily. Process the images produced by the equipment for the analysis and diagnosis of diseases.	2D&3D image view, Import/Export, DIR Media Storage, Print SCU, Storage SCU/SCP, Worklist SCU, Query/Retrieve SCU/SCP, Storage Commitment SCU, MPPS	

Analysis 1 Power supply

Both devices are designed to operate within standard voltage and frequency ranges commonly available in the US market. The Proposed device's power supply parameters are fully compatible with the electrical infrastructure in these regions, ensuring reliable and safe operation. Additionally, the device has been tested and validated to meet all relevant electrical safety standards, confirming that the specified power supply range does not compromise its performance or safety.

Analysis 2 Tube voltage

The tube voltage range of the proposed device is comparable to that of the predicate device for the intended use. The minor difference does not affect image quality, radiation dose, or device performance. Therefore, this variation does not pose any risk to the safety or effectiveness of the device.

Analysis 3 Tube current

The Proposed device's tube current range is sufficient to achieve the intended

diagnostic image quality while maintaining patient safety. The device has been validated to ensure it meets all applicable performance and safety standards, demonstrating that the specified tube current range is appropriate for its intended use. Therefore, this variation does not pose any risk to the safety or effectiveness of the device.

Analysis 4 X-ray generator rated output power
The proposed device's rated output power is lower than that of the predicate device. However, image quality testing confirmed that the system produces diagnostic image quality across all intended scan modes at this power level. The lower rated power contributes to radiation dose management while maintaining clinical utility. This is further supported by an independent clinical image quality assessment,in which an ABR-certified radiologist reviewed sample images from the device and confirmed that the overall image quality was clinically acceptable. Therefore, this difference does not adversely affect safety or effectiveness.

Analysis 5 SID
SID is a design parameter that, together with focal spot size and detector pixel size, influences geometric unsharpness and spatial resolution. The proposed device uses a focal spot size equivalent to that of the predicate device and incorporates pixel sizes that are favorable for spatial resolution to compensate for the SID difference. Measured spatial resolution (IEC 61223-3-7) meets or exceeds clinical requirements. Radiation dose (Kerma/DAP) was also verified and complies with applicable limits. Therefore, the SID difference does not adversely affect safety or effectiveness.

Analysis 6 Active area & Pixel size
The active area of each detector is selected based on the intended FOV for each specific model and is verified to fully cover the corresponding imaging field. The proposed device's pixel sizes are favorable for spatial resolution compared to the predicate device. Measured spatial resolution data (IEC 61223-3-7) confirmed that all models meet the clinical requirements. Therefore, the differences in detector active area and pixel size do not adversely affect imaging performance or clinical utility.

Analysis 7 FOV
The system has been rigorously tested and validated to confirm that the FOV specifications provide sufficient coverage and resolution for its intended diagnostic applications. These differences do not compromise the device's ability to produce high-quality images or its compliance with applicable performance and safety standards. Therefore, the proposed device remains safe and effective for its intended use. Analysis 8 Scan time

This minor variation in scan time is not clinically significant and does not compromise the safety or effectiveness of the device. The difference in scan time is attributed to variations in hardware design and image acquisition algorithms, which do not affect the overall performance, patient safety, or diagnostic efficacy of the device. Therefore, this variation does not pose any risk to the safety or effectiveness of the device.

VII. Non-Clinical Testing

The device described in this summary, were tested and demonstrated to be in conformance with the following standards:

Performance testing：

- IEC 61223-3-7

  All models met the acceptance criteria for spatial resolution (Spatial Resolution Index 10 > 1 lp/mm)CNR (retention ≥60% after constancy test), acceptance index (≥100), uniformity (>5), and artifacts (no ring or geometric artifacts visible). Kiso values were below the 50 mGy limit across all models. After 3,600 exposures simulating 6 months of use, all constancy test results remained within the specified limits.

- IEC 61223-3-4

  Acceptance tests were performed on all four models (mDX-15Pro-K10, mDX-15Pro-Y30, mDX-15Pro-B50, and mDX-15Plus-Y50S) in both panoramic and lateral cephalometric modes. All models met the acceptance criteria for X-ray tube voltage deviation (±10%), total filtration (≥3.5 mm Al), focal spot size (width 0.5-0.75 mm, length 0.7-1.1 mm), radiation output reproducibility (coefficient of variation ≤0.05), and spatial resolution (≥3.1 lp/mm). Low contrast resolution (four holes of 2.5 mm to 1 mm distinguishable), image uniformity (no visible stripe fluctuation), patient positioning lasers, and panoramic focal trough (steel pins clearly visible with left-right symmetry) also passed visual and functional evaluations. The test results confirm that all models comply with the performance requirements of IEC 61223-3-4:2000.

- IEC 60336

  The X-ray tube (Canon D-054SB) used in all models was certified by the manufacturer to comply with IEC 60336:2005.

- ISO 12052

  The workstation software (mDX-15P_WorkstationSystem_V1.0) was tested for network communication (C-ECHO, C-STORE, C-FIND services), media storage and exchange (file format, compression format, CD/DVD and USB media), and data format integrity (core DICOM tags, metadata association, special character support). All test

items passed. The conformance statement was verified to be complete and consistent with actual performance. The software fully complies with the DICOM interoperability requirements of ISO 12052:2017.

Biocompatibility testing

Biocompatibility of patient-contacting components was evaluated perISO 10993-1, -5, -10, and -23. The test article showed no evidence of cytotoxicity, sensitization, or irritation. All test results passed.

Software

Software verification and validation was performed as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance of Premarket Submissions for Software Contained in Medical Devices.". No issues have been identified during the verification and validation Process.

Cybersecurity

The device cybersecurity was evaluated in accordance withFDA Guidance "Cybersecurity in Medical Devices: Quality System Considerationsand Content of Premarket Submissions." No high-risk vulnerabilities wereidentified.

Electrical Safety and EMC

The device was tested for compliance with IEC 60601-1 / ANSI AAMI ES60601-1,IEC 60601-1-2, IEC 60601-4-2, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-63,and IEC 62366-1 through third-party testing. All applicable tests passed.

VIII.Clinical Performance Data

Sample clinical images obtained from the subject device were provided to demonstrate its imaging performance. An ABR-certified radiologist with over 5 years of experience post-certification independently reviewed a number of sample scans and diagnostic images to evaluate different essential image quality related items. The results were documented in the Clinical Performance Evaluation Report. The overall image quality was acceptable.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate device.