November 13, 2025

Fussen Technology Co.,Ltd.
℅ Kyra Kang
Director
Landlink Healthcare Technology (Shanghai) Co., Ltd
Room 1308, Baohua International Plaza, West Guangzhong
Road 555, Jingan District
SHANGHAI, CHINA

Re: K251842
Trade/Device Name: Dental Computed Tomography X-ray System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: October 7, 2025
Received: October 14, 2025

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 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
Diagnostic 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.

510(k) Number *(if known)*

K251842

Device Name

Dental Computed Tomography X-ray System

Indications for Use *(Describe)*

The product is intended to produce X-ray Cone-Beam Computed Tomography, Panoramic tomography and Cephalometric (optional) images. The medical institutions can use the images for diagnostic purposes in oral and maxillofacial regions.The product is intended for use in hospitals and clinics, operated and used by trained professionals under the guidance of a physician.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K251842

I. Submitter

Fussen Technology Co., Ltd
901,1001, Building #D1, Nanshan Zhiyuan, 1001 Xueyuan Avenue, Changyuan Community, Taoyuan Street, Nanshan District, 518055 Shenzhen, Guangdong,PEOPLE'S REPUBLIC OF CHINA
Contact person: Ms. Guiqin Zheng
Position: regulatory affairs
Tel.: 0086-15907673812
E-mail: venus.zheng@fussengroup.com

Preparation date: June 3rd, 2025

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 Computed Tomography X-ray System
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 used for X-ray image diagnosis of oral and maxillofacial region in medical institutions through X-ray cone-beam computed tomography, panoramic and cephalometric photography. The device is intended for use in hospitals and clinics, operated and used by trained professionals under the guidance of a physician.

This device is divided into two models: Matrix 7000(Rubik X1), Matrix 7800(Rubik X3).

The device is composed of X-ray tube head, plate detector, control device, positioning aid, frame, cephalometric positioning shooting aid, workstation software, etc.

V. Indications for use

The product is intended to produce X-ray Cone-Beam Computed Tomography, Panoramic tomography and Cephalometric (optional) images. The medical institutions can use the images for diagnostic purposes in oral and maxillofacial regions. The product is intended for use in hospitals and clinics, operated and used by trained professionals under the guidance of a physician.

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 Computed Tomography X-ray System Model：Matrix 7000(Rubik X1), Matrix 7800(Rubik X3)	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	The product is intended to produce X-ray Cone-Beam Computed Tomography,	Planmeca Viso is a system intended to produce two-dimensional (2D) and three-	Same

use	Panoramic tomography and Cephalometric (optional) images. The medical institutions can use the images for diagnostic purposes in oral and maxillofacial regions. The product is intended for use in hospitals and clinics, operated and used by trained professionals under the guidance of a physician.	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	
Device Structure	The product is composed of X-ray tube head, plate detector, control device, positioning aid, frame, cephalometric positioning shooting aid, workstation software, etc.	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	AC 120 V (US)/230 V (EU) V, 60Hz (US)/50 Hz (EU)	AC 100-220V 50/60Hz, 230-240V, 50Hz	Analysis 1
Patient population	pediatric and adult patients	pediatric and adult patients	Same
Clinical conditions	The product is intended for use in hospitals and clinics.	This X-ray unit is intended to be used in a professional healthcare environment such as dental offices, clinics and similar environments.	Same
Dimenson	1650 (L) × 1840 (W) × 2250 (H) (mm)	1540 (L) × 2160 (W) × 2340 (H) (mm)	Similar
Tube voltage	60-120kV	60-120kV	Same
Tube current	2-10mA	2-16mA	Analysis 2
X-ray generator rated	1.2kW	1.6kW	Analysis 3

output power				
Focus nominal value		0.5 mm	0.5 mm	Same
Pixel size（mm）		0.3-0.05	0.6-0.075	Analysis 4
SID（Source Image Distance）		CT photography: 635mm	CT photography: 700mm	Analysis 5
		Panorama photography: 635mm	Panorama photography: 700mm	
		Cephalometric photography: 1722mm	Cephalometric photography: 1700mm	
Active area&Pixel size	CT	153.6*153.6mm, 100um(Matrix 7000(Rubik X1)); 204.8*204.8mm, 100um(Matrix 7800(Rubik X3))	247.7*301.1mm，139um	Analysis 6
	PANO	153.6*153.6mm, 100um(Matrix 7000(Rubik X1)); 204.8*204.8mm, 100um(Matrix 7800(Rubik X3))	8.896/17.792*166.8mm，139um	
	CEPH	225.2mm×6.8mm, 100um(Matrix 7000(Rubik X1)); 250mm×300mm, 125um(Matrix 7800(Rubik X3))	301.82*248.9mm，131um	
FOV		Matrix 7000(Rubik X1): 16cm*16cm, 16cm*10cm, 12cm*10cm, 9cm*9cm, 8cm*9cm, 5cm*5cm; Matrix 7800(Rubik X3): 18cm×20cm, 18cm×13cm, 16cm×11cm, 12cm×10cm, 9cm×9cm, 8cm×9cm, 5cm×5cm	26*30，16*16，14*10，10*10，5*5	Analysis 7
Scan time		Max 30s(Matrix 7000(Rubik X1)); Max 24s(Matrix 7800(Rubik X3))	Max 36s	Analysis 8
Software	Compatibility	Dicom 3.0 format compatible	Dicom 3.0 format compatible	Similar
	Name	DTKL	Planmeca Romexis	
	Fun	Patient information	2D&3D image view,	

	ctio n	management, image acquisition, image viewing, transmission and output functions	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 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 3 X-ray generator rated output power
The Proposed device's output power of 1.2 kW is sufficient to generate the necessary X-ray beam quality and intensity for high-quality diagnostic imaging. The system has been designed and validated to ensure optimal performance within this power range, meeting all relevant diagnostic requirements while maintaining patient safety. Comprehensive testing and verification have confirmed that the device operates safely and effectively at 1.2 kW. This variation does not pose any risk to the safety or effectiveness of the device.

Analysis 4 Pixel size
The Proposed device's smaller pixel size range provides higher spatial resolution, enabling more detailed and precise imaging compared to the predicate device. This enhancement improves diagnostic capability without compromising patient safety or system performance. The device has been rigorously tested and validated to ensure it meets all applicable standards for image quality, accuracy, and safety. This variation does not pose any risk to the safety or effectiveness of the device.

Analysis 5 SID
The slight variations in distance are within the acceptable range for diagnostic accuracy and do not compromise the system's ability to produce clinically relevant images. The device has been thoroughly tested and validated to meet all applicable performance and safety standards, confirming that these differences do not affect its diagnostic capabilities or safety profile. This variation does not pose any risk to the safety or effectiveness of the device.

Analysis 6 Active area&Pixel size

The Proposed device's Active area&Pixel size are designed to provide high-resolution imaging, ensuring diagnostic accuracy and clarity. The system has been rigorously tested and validated to meet all applicable performance and safety standards, confirming that these differences do not affect its clinical utility or safety profile. This variation does not pose any risk to the safety or effectiveness of the device.

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 registered product 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
- IEC 61223-3-4
- IEC 60336
- ISO 12052

Biocompatibility testing

Biocompatibility of the device was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1" The following testing was conducted:

- ISO 10993-1
- ISO 10993-5
- ISO 10993-10
- ISO 10993-23

Software

Guidance for Industry and Food and Drug Administration Staff-Content of Premarket Submissions for Device Software Functions

Cybersecurity

Guidance for Industry and Food and Drug Administration Staff-Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions

Electrical Safety and EMC

- 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
- IEC 62366-1

A non-clinical testing evaluation was performed to demonstrate the image quality and performance of the device.

VIII. Clinical Testing

Images were acquired of phantoms and human subjects (including adults and pediatric patients of varying ages and genders) using a range of different detectors and system modes. These images were subsequently evaluated by a qualified radiographer who confirmed that the overall image quality was clinically adequate for its intended use.

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.