



September 30, 2026

Fussen Technology Co., Ltd.
% Guiqin Zheng
regulatory affairs
901,1001, Bldg. #D1, Nanshan Zhiyuan, 1001 Xueyuan Ave., Changyuan Community, Taoyuan St.,
Nanshan District
SHENZHEN, GUANGDONG 518055
CHINA

Re: K263033

Trade/Device Name: Dental Computed Tomography X-ray System (Rubik XSmart, Rubik X1, Rubik X3) (Matrix 7000, Matrix 7800)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: August 31, 2026
Received: August 31, 2026

Dear Guiqin Zheng:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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, 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

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.

K263033

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Please provide the device trade name(s).

?

Dental Computed Tomography X-ray System (Rubik XSmart, Rubik X1, Rubik X3) (Matrix 7000, Matrix 7800)

Please provide your Indications for Use below.

?

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.

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

?

Please select the age group(s) for which the device(s) is to be used.

☐ Neonates/Newborns (Birth to < 29 days old)

☐ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) Summary K263033

I. Submitter

Fussen Technology Co., Ltd

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Contact person: Ms. Guiqin Zheng

Position: regulatory affairs

Tel.: 0086-15907673812

E-mail: venus.zheng@fussengroup.com

Preparation date: August 5, 2026

II. Proposed Device

Device Trade Name:	Dental Computed Tomography X-ray System(Rubik X1, Rubik X3)
Common name:	Computed tomography x-ray system.
Regulation Number:	21 CFR 892.1750
Regulatory Class:	Class II
Product code:	OAS
Review Panel:	Radiology
510(k) number:	K263033

III. Predicate Devices

510(k) Number:	K251842
Trade name:	Dental Computed Tomography X-ray System(Rubik X1, Rubik X3)
Common name:	Computed tomography x-ray system.
Classification:	Class II
Product Code:	OAS
Manufacturer	Fussen Technology Co., Ltd

IV. Device description

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.

This device is divided into two models: Matrix 7000, Matrix 7800.

This product is composed of X-ray tube, flat panel detector, control device, positioning aid, frame, cephalometric positioning shooting aid (Optional), 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 (K251842)	Discussion
Trade name	Dental Computed Tomography X-ray System(Rubik X1, Rubik X3)	Dental Computed Tomography X-ray System(Rubik XSmart, Rubik X1, Rubik X3)	/
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

Characteristics	Proposed device	Predicate device (K251842)	Discussion
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.	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.	Same
Device Structure	This product is composed of X-ray tube, flat panel detector, control device, positioning aid, frame, cephalometric positioning shooting aid, workstation software, etc.	This product is composed of X-ray tube, flat panel detector, control device, positioning aid, frame, cephalometric positioning shooting aid (Optional), workstation software, etc.	Similar
Power supply	AC 120 V (US)/230 V (EU) V, 60Hz (US)/50 Hz (EU)	AC 120 V (US)/230 V (EU) V, 60Hz (US)/50 Hz (EU)	Same
Patient population	pediatric and adult patients	pediatric and adult patients	Same
Clinical conditions	The product is intended for use in hospitals and clinics.	The product is intended for use in hospitals and clinics.	Same
Dimension	1650 (L) × 1840 (W) × 2250 (H) (mm)	1650 (L) × 1840 (W) × 2250 (H) (mm)	Same
Tube voltage	60-120kV	60-120kV	Same
Tube current	2-10mA	2-10mA	Same
X-ray generator rated	1.2kW	1.2kW	Same

Characteristics		Proposed device	Predicate device (K251842)	Discussion
output power				
Focus nominal value		0.5 mm	0.5 mm	Same
Voxel size (mm)		0.3-0.05	0.3-0.05	Same
SID (Source Image Distance)		CT photography: 635mm	CT photography: 635mm	Same
		Panorama photography: 635mm	Panorama photography: 635mm	
		Cephalometric photography: 1722mm	Cephalometric photography: 1722mm	
Active area & Pixel size	CT	153.6*153.6mm, 100um(Matrix 7000); 204.8*204.8mm, 100um(Matrix 7800)	153.6*153.6mm, 100um(Matrix 7000); 204.8*204.8mm, 100um(Matrix 7800)	Same
	PANO	153.6*153.6mm, 100um(Matrix 7000); 204.8*204.8mm, 100um(Matrix 7800)	153.6*153.6mm, 100um(Matrix 7000); 204.8*204.8mm, 100um(Matrix 7800)	
	CEPH	225.2mm*6.8mm, 100um(Matrix 7000); 250mm*300mm, 125um(Matrix 7800)	225.2mm*6.8mm, 100um(Matrix 7000); 250mm*300mm, 125um(Matrix 7800)	
FOV		Matrix 7000: 16cm*16cm, 16cm*10cm, 12cm*10cm, 9cm*9cm, 8cm*9cm, 5cm*5cm; Matrix 7800: 18cm*20cm, 18cm*13cm, 16cm*11cm, 12cm*10cm, 9cm*9cm,	Matrix 7000 Configuration 1: 16cm*16cm, 16cm*10cm, 12cm*10cm, 9cm*9cm, 8cm*9cm, 5cm*5cm; Matrix 7000 Configuration 2: 16cm*16cm(Optional), 16cm*10cm, 12cm*10cm, 9cm*9cm, 8cm*9cm, 5cm*5cm; Matrix 7800: 18cm*20cm, 18cm*13cm, 16cm*11cm, 12cm*10cm, 9cm*9cm, 8cm*9cm, 5cm*5cm	Similar

Characteristics		Proposed device	Predicate device (K251842)	Discussion
		8cm×9cm, 5cm×5cm		
Scan time		Max 30s(Matrix 7000); Max 24s(Matrix 7800)	Max 30s(Matrix 7000); Max 24s(Matrix 7800)	Same
Software	Compati- bility	DICOM 3.0 format compatible	DICOM 3.0 format compatible	Same
	Name	DTKL	DTKL	
	Function	Patient information management, image acquisition, image viewing, transmission and output functions	Patient information management, image acquisition, image viewing, transmission and output functions	
3D Scan mode		√	Matrix 7000 Configuration 1: √ Matrix 7000 Configuration 2: × Matrix 7800: √	Similar

VII. Non-Clinical Testing

The devices 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

VIII. Clinical Testing

No clinical study is included in this submission.

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.