June 27, 2025

Yian Medical Technology (Haining) Co., Ltd.
% Lili Yan
Director of Regulatory Affair Center
1st Floor Area 1, 2nd Floor Area 1, Building A, No. 2
Caohejing Road, Haining Economic Development Zone, Haichang
HAINING, JIAXING 314400
CHINA

Re: K251642
Trade/Device Name: Dental CBCT X-ray System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: April 28, 2025
Received: May 29, 2025

Dear Lili Yan:

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,

FDA Digitally signed by Gabriela M. Rodal -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological 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)*
K251642

Device Name
Dental CBCT X-ray System

Indications for Use *(Describe)*
Hasla is intended to produce two-dimensional digital x-ray images including panoramic and cephalometric image, and three-dimensional digital x-ray images of the dental, oral, maxillofacial region, at the direction of healthcare professionals as diagnostic support for adult and pediatric patients.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.

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.

奕安医疗
YIAN MEDICAL

510(k) Summary

Date Prepared: April 28, 2025

Submitter: Yian Medical Technology (Haining) Co., Ltd
1st Floor Area 1, 2nd Floor Area 1, Building A, No. 2 Caohejing Road, Haining Economic Development Zone, Haichang Street, Haining City, Jiaxing City, Zhejiang Province, China

Contact Person: Lili YAN
Director of Regulatory Affair Center
Yian Medical Technology (Haining) Co., Ltd
Tel: +86-0573-89739736
E-mail: lili.yan@yian-medical.com

Identification of the Device:

Proprietary/Trade Name:	Dental CBCT X-ray System
Device Name:	Dental CBCT X-ray System
Model:	Hasla
Classification Name:	Computed tomography x-ray system
Regulatory Number:	21 CFR Part 892.1750
Product Code:	OAS
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate Device:

Trade Name:	/
Device Name;	Dental Cone-beam Computed Tomography
Model Name:	iDT901X1
Classification Name:	Computed tomography x-ray system
Regulatory Number:	21 CFR Part 892.1750
Product Code:	OAS
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Yian Medical Technology (Haining) Co., Ltd.
Clearance:	K232710 (cleared 8， Jan. , 2023)

奕安医疗 YIAN MEDICAL

Device Description:

The product （Dental CBCT X-ray System, Model: Hasla) uses cone-beam computed tomography (CBCT) through X-ray cone-beam, panoramic radiography, cephalometric radiography to produce images of the dental, oral and maxillofacial areas to provides diagnostic details for the medical facilities. This product consists of Frame, X-ray generator (including Integrated X-ray source tube head, X-ray tube, Collimator), Image receptor and Image processing system (including Computer, Monitor, and Software workstation).

Following modifications were made to the predicate device Dental Cone-beam Computed Tomography, Model: iDT901X1 (K232710). Yian Medical Technology (Haining) Co.,Ltd. submits this special 510(k) to request clearance for the subject device Dental CBCT X-ray System, Model: Hasla.

Item	Cleared device iDT901X1 Dental Cone Beam-computed Tomography (K232710)	Modified device Hasla Dental CBCT X-ray System
Model	iDT901X1	Hasla
Labeling	Product name: Dental Cone Beam-computed Tomography Model Name: iDT901X1	Product name: Dental CBCT X-ray System Model name: Hasla

Indications for Use:

Hasla is intended to produce two-dimensional digital x-ray images including panoramic and cephalometric image, and three-dimensional digital x-ray images of the dental, oral, maxillofacial region, at the direction of healthcare professionals as diagnostic support for adult and pediatric patients.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.

Standards:

- IEC60601-1 Edition 3.2 2020-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]

- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC /TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 60601-1-3 Edition 2.2 2021-01 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366-1 Edition 1.1 2020-06 Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- IEC 60601-2-63 Edition 1.1 2017-07 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 61223-3-4:2000 Evaluation and routine testing in medical imaging departments - Part 3-4: Acceptance tests - Imaging performance of dental X-ray equipment
- IEC 61223-3-7 Edition 1.0 2021-12 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
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices — Part 23: Tests for irritation
- ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements
- ISO 20417: 2021 Medical devices - Information to be supplied by the manufacturer
- ISO 14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices
- ISO 12052:2017 Health informatics — Digital imaging and communication in medicine (DICOM) including workflow and data management

- IEC 60825-1:2014 Edition 3.0 Safety of laser products - Part 1: Equipment classification and requirements

FDA Guidance Documents:

- *Electronic Submission Template for Medical Device 510(k) Submissions* issued on October 2, 2023
- *The Special 510(k) Programme* issued on September 13,2019
- Electromagnetic Compatibility (EMC) of Medical Devices Guidance for Industry and Food and Drug Administration Staff JUNE 2022
- Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff NOVEMBER 2017
- Premarket Assessment of Pediatric Medical Devices Guidance for Industry and FDA Staff MARCH 2014
- Content of Premarket Submissions for Device Software Functions issued on June 2023
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices issued on September 2016
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions issued on September 2023

Performance standard:

- 21CFR PART 1010 PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL
- 21 CFR 1020.30: Diagnostic x-ray system and their major components
- 21 CFR 1020.31: Radiographic Equipment
- 21 CFR 1020.33 Computed tomography (CT) equipment

Comparison with Predicate Device:

The Dental CBCT X-ray System (Model: Hasla） and its predicate device, have the same indication for use, functions, physical characteristics, performance characteristics. They are equivalent in model name.

Substantial equivalence

The comparison between the overall specifications of the predicate device (Dental Cone-beam Computed Tomography, Model: iDT901X1)) and the subject device (Dental CBCT X-ray System, Model: Hasla)) is shown in Table 1. Any difference between the predicate device and the subject device have no impact on safety or efficacy of the subject device and do not raise any new potential or increased safety risks.

	Subject Device Dental CBCT X-ray System (Model: Hasla）	Predicate Device Dental Cone-beam Computed Tomography (Model:iDT901X1） (K232710)
Model	Hasla	iDT901X1
Trade Name	Dental CBCT X-ray System	/
Product Code	OAS	OAS
Regulation Number	21 CFR 892.1750	21 CFR 892.1750
Regulation Name	OAS: Computed tomography x-ray system	OAS: Computed tomography x-ray system
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental
Indications for use	Hasla is intended to produce two-dimensional digital x-ray images including panoramic and cephalometric image, and three-dimensional digital x-ray images of the dental, oral, maxillofacial region, at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements	Dental Cone-beam Computed Tomography is intended to produce two-dimensional digital x-ray images including panoramic and cephalometric image, and three-dimensional digital x-ray images of the dental, oral, maxillofacial region, at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm

	Subject Device Dental CBCT X-ray System (Model: Hasla）	Predicate Device Dental Cone-beam Computed Tomography (Model:iDT901X1） (K232710)
	approximately correspond to that of an average 5 year old.	(44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old.
Target Population	For patients 6 years and older	For patients 6 years and older
Anatomical Site	The dental, oral, maxillofacial region	The dental, oral, maxillofacial region
Users	Health care professionals	Health care professionals
Patient Contact Material	Meet ISO 10993 series standard	Meet ISO 10993 series standard
Sterility	Non-sterile	Non-sterile
Tube Voltage	60kV~120kV	60kV~120kV
Tube Current	1 mA～20 mA	1 mA～20 mA
Nominal Focal Spot Size	0.5	0.5
Pulse Exposure function	Yes	Yes
Power	Frequency: 50/60Hz Voltage: 110-120VAC Power: 3.0KVA	Frequency: 50/60Hz Voltage: 110-120VAC Power: 3.0KVA
Detector	FPD（TFT）	FPD（TFT）
material	CsI	CsI
Pixel Size	200μm x 200μm (With binning) (CT, Cephalometric)	200μm x 200μm (With binning) (CT, Cephalometric)

	Subject Device Dental CBCT X-ray System (Model: Hasla）	Predicate Device Dental Cone-beam Computed Tomography (Model:iDT901X1）(K232710)
	100μm x 100μm（Without binning）(CT, Panoramic)	100μm x 100μm（Without binning）(CT, Panoramic)
Pixel Number	1504*1248(With binning) (CT, Cephalometric) 800*2496(Without binning) (CT) 3008*65(Without binning) (Panoramic) 1504*1248(With binning) (Cephalometric)	1504*1248(With binning) (CT, Cephalometric) 800*2496(Without binning) (CT) 3008*65(Without binning) (Panoramic) 1504*1248(With binning) (Cephalometric)
Size of Area Receiving X-ray	300.8mm x 249.6mm (CT, CEPH) 80mm x 249.6mm (CT) 300.8mm x 6.5mm (PANO)	300.8mm x 249.6mm (CT, CEPH) 80mm x 249.6mm (CT) 300.8mm x 6.5mm (PANO)
spatial resolution	5lp/mm	5lp/mm
Number of Bits	16bits	16bits
SID/SOD	SID: 750mm/490mm	SID: 750mm/490mm
Dimension (WxDxH)	Max.overall dimension 1300mm*1272mm*2365mm	Max.overall dimension 1300mm*1272mm*2365mm
Weight	233kg±5kg	233kg±5kg

	Subject Device Dental CBCT X-ray System (Model: Hasla）	Predicate Device Dental Cone-beam Computed Tomography (Model:iDT901X1）(K232710)
Imaging Mode	CBCT, PANO, CEPH	CBCT, PANO, CEPH
Panoramic Scan Performance (Scan Time)	15sec	15sec
Cephalometric Radiography (Scan Time)	2.3sec	2.3sec
CT Scan Time	22sec	22sec
CT FOV (Voxel Size)	Diameter 230 mm x 180mm （0.45mm) Diameter 150 mm x 120mm (0.29mm) Diameter 80 mm x 80mm (0.15mm) Diameter 50 mm x50mm (0.097mm) Diameter 50 mm x 50mm (0.071mm)	Diameter 230 mm x 180mm （0.45mm) Diameter 150 mm x 120mm (0.29mm) Diameter 80 mm x 80mm (0.15mm) Diameter 50 mm x50mm (0.097mm) Diameter 50 mm x 50mm (0.071mm)
Software functions	-image acquisition -data management -image display -image processing -System Settings	-image acquisition -data management -image display -image processing -System Settings
Software level of documentation	Basic Documentation Level	Basic Documentation Level
Applied Standards		

	Subject Device Dental CBCT X-ray System (Model: Hasla）	Predicate Device Dental Cone-beam Computed Tomography (Model:iDT901X1）(K232710)
Electrical Safety Standard	ANSI/AAMI ES60601-1 IEC 60601-1	ANSI/AAMI ES60601-1 IEC 60601-1-2
Electromagnetic Compatibility Standard	IEC 60601-1-2	IEC 60601-1-2
Radiation Safety Standard	IEC 60601-1-3	IEC 60601-1-3
Electrical Equipment Usability Safety	IEC 60601-1-6	IEC 60601-1-6
Usability Engineering Standard	IEC 62366	IEC 62366
Software Lifecycle Process Standard	IEC 62304	IEC 62304
Essential performance of dental extra-oral X ray equipment Standard	IEC 60601-2-63	IEC 60601-2-63
Acceptance tests of Imaging performance of computed tomography X-ray	IEC 61223-3-4 IEC 61223-3-7	IEC 61223-3-4 IEC 61223-3-7

	Subject Device Dental CBCT X-ray System (Model: Hasla）	Predicate Device Dental Cone-beam Computed Tomography (Model:iDT901X1） (K232710)
equipment Standard		
Laser Safety standard	IEC 60825-1	IEC 60825-1
Risk Management Standard	ISO 14971	ISO 14971
DICOM Standard	ISO 12052:2017	ISO 12052:2017
Biocompatibility Standard Compliance	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23

Table 1

The subject device and the predicate device are equivalent in the model name, same in the indications for use, patient population, use environment, software functions, and software level of documentation, performance characteristics and technical specification. The differences between the proposed device and the predicate device will not raise any new issues of safety or effectiveness.

Summary of Testing:

Summary of Non-Clinical Tests:
Electrical Safety and Electromagnetic Compatibility Summary

The electrical safety and EMC data included in previous submission is valid for the subject device of this submission and is in compliance with the following FDA recognized standards:

•IEC60601-1 Edition 3.2 2020-08

•ANSI/AAMI ES: 60601-1:2005/A2:2010/AMD2:2021

•IEC 60601-1-2 Edition 4.1 2020-09

•IEC /TR 60601-4-2 Edition 1.0 2016-05

•IEC 60601-1-3 Edition 2.2 2021-01

•IEC 60601-1-6 Edition 3.2 2020-07

•IEC 60601-2-63 Edition 1.2 2017-07

Bench Testing Summary

The modifications of the device have no impact on the product's design, working principle, software function, software documentation level, performance characteristic and technical specification indication for use, patient population, environment of use, user needs, thus no impact on the previously conducted Bench Testing and validation. No new bench testing or validation was needed.

The previously conducted and submitted verification and validation test results are still valid for the modified device and is in compliance with the above standards, regulations and performance standards. The non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as the predicate device.

Summary of Clinical Tests:

The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Dental CBCT X-ray System (Model: Hasla) is substantially equivalent to the predicate devices.