January 9, 2024

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

Re: K232710
Trade/Device Name: Dental Cone-beam Computed Tomography
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: December 14, 2023
Received: December 26, 2023

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232710

Device Name
Dental Cone-beam Computed Tomography

Indications for Use *(Describe)*

Dental Cone-beam Computed Tomography (Model:iDT901X1) 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.

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510(k) Summary
K232710

Date Prepared: Jun 30, 2023

Manufacturer: 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
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Yian Medical Technology (Haining) Co., Ltd
Tel: +86-0573-89739736
E-mail: lili.yan@yian-medical.com

Identification of the Device:

Proprietary/Trade Name: /
Device Name: Dental Cone-beam Computed Tomography
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: PreXion3D Explorer PRO, Model P03B
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: PreXion Corporation
Clearance: K221525 (cleared July 22, 2022)

Device Description:

The product （Product Name: Dental Cone-beam Computed Tomography, Model:iDT901X1) 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, Software workstation).

Indications for Use:

Dental Cone-beam Computed Tomography (Model:iDT901X1) 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:

- Format for Traditional and Abbreviated 510(k)s Guidance 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 Guidance for Industry and Food and Drug Administration Staff JUNE 2023
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff SEPTEMBER 2016
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff 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 Cone-beam Computed Tomography (Model:iDT901X1） and its predicate device, have the equivalent intended use, functions and similar physical characteristics, performance characteristics.

Substantial Equivalence:

The comparison between the overall specifications of predicate device (PreXion3D Explorer PRO, model P03B) and the new device (Dental Cone-beam Computed Tomography (Model:iDT901X1）) is shown in Table 1. Any differences between the predicate and the new device have no impact on safety or efficacy of the new device and do not raise any new potential or increased safety risks, and the new device is equivalent in performance to existing legally marketed devices.:

	Subject Device Dental Cone-beam Computed Tomography (Model:iDT901X1）	Predicate Device P03B (K221525)
Manufacturer	Yian Medical Technology (Haining) Co., Ltd.	PreXion Corporation
Trade Name	/	PreXion3D Explorer PRO
Product Code	OAS	OAS
Regulation	21 CFR 892.1750	21 CFR 892.1750

	Subject Device Dental Cone-beam Computed Tomography (Model:iDT901X1）	Predicate Device P03B (K221525)
Number		
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	Dental Cone-beam Computed Tomography (Model:iDT901X1） 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.	PreXion3D Explorer PRO 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, ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. Cephalometric imaging also includes the hand and wrist to obtain carpus images for growth and maturity assessment. 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.

	Subject Device Dental Cone-beam Computed Tomography (Model:iDT901X1）	Predicate Device P03B (K221525)
Target Population	Children aged 6 (except infants) to elderly	Children aged 6 (except infants) to elderly
Anatomical Site	The dental, oral, maxillofacial region	The dental, oral, maxillofacial region ENT (Ear, Nose and Throat) and neck 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	90-110KV
Tube Current	1 mA～20 mA	1-5.3mA
Focal Spot Size	0.5	0.3mm x 0.3mm
Pulse Exposure function	Yes	Yes
Power	Frequency: 50/60Hz Voltage: 110-120VAC Power: 3.0kVA	Frequency: 50/60Hz Voltage: 110-240VAC Power: 1.0KVA
Detector	FPD（TFT）	FPD (TFT)
material	CsI	CsI:Tl / Gd2 O2 S:Tb
Pixel Size	200μm x 200μm (With binning) (CT, Cephalometric) 100μm x 100μm （ Without binning）(CT, Panoramic)	248 μm x248μm (With binning) (CT, CT-Panoramic, Panoramic) 124 μm x124μm (Without binning) (CT, CT-Panoramic, Panoramic, Ceph)
Pixel Number	1504*1248(With binning) (CT, Cephalometric)	1024x1280(With binning) (CT, CT-Panoramic)

	Subject Device Dental Cone-beam Computed Tomography (Model:iDT901X1）	Predicate Device P03B (K221525)
	800*2496(Without binning) (CT) 3008*65(Without binning) (Panoramic) 1504*1248(With binning) (Cephalometric)	2560x2048 (Without binning) (CT, CT-Panoramic, Ceph) 1900 x 120 (Panoramic) 2560 x 2048 (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)	253.95mm x 317.44mm (CT, CT-Panoramic) 230mm x 15mm (Panoramic) 239mm x 302mm (Ceph)
spatial resolution	5lp/mm	4lp/mm
Number of Bits	16bits	16bits
SID/SOD	SID: 750mm/490mm	700mm/ 420mm (CT, CT-Panoramic, Panoramic) 1000mm / 840mm (Ceph)
Dimension (WxDxH)	Max. 1300mm*1272mm*2365mm.	1,112 mm x 1,558 mm x 2330 mm (CT, CTPanoramic, Panoramic) 1164 mm x 1690 mm x 2330 mm (with Ceph)
Weight	233kg±5kg	230 kg (CT, CTPanoramic, Panoramic, Ceph)
Imaging Mode	CBCT, PANO, CEPH	CT scan, CT-Panoramic, Panoramic scan, Cephalometric radiography

	Subject Device Dental Cone-beam Computed Tomography (Model:iDT901X1）	Predicate Device P03B (K221525)
Panoramic Scan Performance (Scan Time)	15sec	8-16sec
Cephalometric Radiography (Scan Time)	2.3sec	0.16sec
CT Scan Time	22s	10-20sec
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 150mm x H156mm (0.100 - 0.200mm) Diameter 150mm x H100mm (0.100 - 0.200mm) Diameter 100mm x H100mm (0.100 - 0.200mm) Diameter 50mm x H50mm (0.100 - 0.200mm)
Software functions	-image acquisition -data management -image display -image processing -System Settings	-Image acquisition -Data management -Display High-resolution 2D and 3D Images Function -Image Processing Function includes Airway measurement -system setting
Software level of documentation	Basic Documentation Level	Basic Documentation Level

	Subject Device Dental Cone-beam Computed Tomography (Model:iDT901X1）	Predicate Device P03B (K221525)
Electrical Safety Standard	ANSI/AAMI ES60601-1	ANSI/AAMI ES60601-1
Electromagnetic Compatibility Standard	IEC 60601-1-2	IEC 60601-1-2
Radiation Safety Standard	IEC 60601-1-3	IEC 60601-1-3
Electrical Equipment	IEC 60601-1-6	IEC 60601-1-6
Usability Safety Usability Engineering Standard	IEC 62366	IEC 62366
Software Lifecycle Process Standard	IEC 62304	IEC 62304
Essential performance of dental extra-oral Xray equipment Standard	IEC 60601-2-63	IEC 60601-2-63
Acceptance tests of Imaging performance of dental X-ray equipment Standard	IEC 61223-3-4	IEC 61223-3-4
Acceptance tests of Imaging performance of computed tomography X-ray equipment Standard	IEC 61223-3-7	IEC 61223-3-5
Laser Safety		

	Subject Device Dental Cone-beam Computed Tomography (Model:iDT901X1）	Predicate Device P03B (K221525)
Standard Risk Management Standard DICOM Standard Biocompatibility Standard Compliance	IEC 60825-1 ISO 14971 ISO 12052:2017 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	IEC 60825-1 ISO 14971 NEMA PS 3.1 - 3.20 ISO 10993-1 ISO 10993-5 ISO 10993-10

The subject device and the predicate device are equivalent in the indications for use, patient population, use environment, software functions, software level of documentation and performance characteristics. They are similar in 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 the submission 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 verification test results showed compliance with the above standards, regulations and performance standards. Validation was performed for overall operation by taking and reviewing test images. 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 device of this premarket submission, sample clinical images were provided to support a decision of substantial equivalence. The iDT901X1 device performance has been clinically evaluated. One US radiation-board certified experienced radiologists has studied independently a number of sample scans and diagnostic images to score different essential image quality related items. The results have been summarized in the image evaluation study report. The overall image quality was acceptable for all cases and image types in various scanning mode for both adult and pediatric.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device, Dental Cone-beam Computed Tomography (Model：iDT901X1) is substantially equivalent to the predicate devices.