April 17, 2025

Yofo Medical Technology Co., Ltd.
% Li Zhao
Senior engineer
Building A1, National Health Industrial Park,
Hi-tech Industrial Development Zone
Hefei, Anhui 230000
CHINA

Re: K243337
Trade/Device Name: Dental Cone Beam Computed Tomography System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: October 25, 2024
Received: March 20, 2025

Dear Li Zhao:

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 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.

Submission Number *(if known)*

K243337

Device Name

Dental Cone Beam Computed Tomography System

Indications for Use *(Describe)*

The Dental Cone Beam Computed Tomography System is intended to be used by medical institutions for X-ray image diagnosis on oral and maxillofacial areas through X-ray Cone Beam Computed Tomography (CBCT).

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.

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510(k) Summary

K243337

1. Contact Details

Applicant Name:	Yofo Medical Technology Co., Ltd.
Applicant Address:	Building A1, National Health Industrial Park, Hi-tech Industrial Development Zone, Hefei, Anhui, 230000, P.R. China
Applicant Contact Telephone:	0551-65770683
Applicant Contact:	Li Zhao
Applicant Contact Email:	li.zhao@yofomedical.com

2. Device Name

Device Trade Name:	Dental Cone Beam Computed Tomography System
Common Name:	X-ray, Tomography, Computed, Dental
Classification Name:	Computed tomography x-ray system
Regulation Number:	892.1750
Product Code:	OAS
Regulation Class:	II

3. Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
K162085	i-CAT FLX V series / KaVo 3D eXam+ V series	OAS

4. Device Description Summary

The system consists of X-ray tube assemblies, collimators, flat panel detector, control devices (the touch screen, the control panel, the console panel and the exposure switch), auxiliary positioning devices(the lifting seat and the chin rest) and U-shape gantry (the X-ray tube assembly support, the base and the Detector Support), and workstation. The system is an open design that allows patients to sit upright during a procedure. An electric powered seat is built into the scanner for proper patient positioning.

The system has 2 configurations: the Configuration 1 has two X-ray tube assemblies(X-ray tube assembly A and X-ray tube assembly B) and two collimators(A and B), the Configuration 2 only has X-ray tube assembly A and collimator A.
The proposed device is a CBCT dental system utilizes X-ray to obtain cross-sectional images of patient's oral and maxillofacial areas. The image software can reconstruct data and clearly display the 3D anatomical structure of the oral and maxillofacial areas, and achieve the multi-slice at any level, accurate measurement, contour plots and so on in the workstation software, greatly facilitating the clinical application of stomatology.

The Lifting Seat moves up and down via buttons on the system Control Panel allowing positioning and adjustment of patients at different heights; the Touch Screen facilitates the adjustment of projection parameters and the control of actions of the device; the Gating and the shielding door are the safety interlock of the X-ray beam exposure to prevent the dose leakage caused by abnormal operation; the Exposure Switch controls the exposure output of the whole machine in real time during the scanning process.

There are four FOV sizes; 20cm x 18cm high resolution is for diagnostic imaging of maxillary region, mandibular region, TMJ region and other craniofacial region, and it is only available for configuration 1; 17cm x 10.5cm high resolution , 8cm x8cm Super Resolution and 4cm x4cm Super Resolution are for diagnostic imaging of maxillary region and mandibular region. Under High Resolution mode, patients will receive lower radiation dose compared to Super Resolution. Dose radiation for each mode is different for pediatric and adult patients.

5. Indications for Use

The Dental Cone Beam Computed Tomography System is intended to be used by medical institutions for X-ray image diagnosis on oral and maxillofacial areas through X-ray Cone Beam Computed Tomography (CBCT).

6. Technological Comparison

Table 1 Comparison of the Subject and Predicate Device

Characteristics	**Subject device** **Dental Cone Beam Computed Tomography System**	**Predicate Device** **i-CAT FLX/KaVo 3D eXam+ series**	Conclusion
Indication for use	The Dental Cone Beam Computed Tomography System is intended to be used by medical institutions for X-ray image diagnosis on oral	Devices of the i-CAT family consist of an x-ray system that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume	Similar.1.

	and maxillofacial areas through X-ray Cone Beam Computed Tomography (CBCT).	reconstructions of the head area, which includes ENT and maxillofacial areas (such as TM Joint studies, mandible & maxilla for implant planning, sinuses, airway), for use in planning and diagnostic support in adult and pediatric care. Devices of the i-CAT family comprise a package of software modules capable of handling 2D and 3D data. This includes 3D reconstruction, storage, retrieval, viewing, and processing of 2D and 3D-image data. The proposed indications for use above of i-CAT FLX / KaVo 3D eXam+ include specification of airway within the ENT and maxillofacial area. The proposed device has been verified and validated to satisfy the requirements derived from the indications for use.	
principle of Operation	Cone Beam X-ray	Cone Beam X-ray	Same
Generator	High Frequency, Constant Potential	High Frequency, Constant Potential	Same
X-ray tube	Stationary anode	Stationary anode	Same
Tube Voltage	80kV~100kV	120 kV(peak)	Similar.2.
Tube Current	2-12 mA, 2-10mA	3-7 mA	Similar.3.
Target material	Tungsten	Tungsten	Same
Focal spot	0.5 mm	0.5 mm	Same
Anode capacity	49 kHU	30 kHU	Similar.4.
Detector*			
Type	Amorphous Silicon	Amorphous Silicon	Same
Total Pixel Area	153.6 mm x 153.6 mm	19.5 x 24.4 cm	Similar.5.
Pixel Matrix	1536 x1536	1536 x 1920	Similar.6.
Pixel Pitch	100μm^2	127 μm^2	Similar.7.

Energy Range	40-160 kVp	40 -160 kVp	Same
Gantry			
Resolution angle / Orbital angle	360°	360°	Same
Orientation	Vertical	Vertical	Same

Difference analysis of subject device and predicate device

No.	Affect and difference analysis
Similar.1.	The actual indication for use of subject and predicate device is the same, subject device does not summarize all the product function in indication for use.
Similar.2.	The tube voltage in the subject device indicates a range of 80kV to 100kV, the tube voltage of predicate device indicates a 120kV peak.
Similar.3.	The range of tube current in the subject device is broader than the predicate device.
Similar.4.	Subject device has slightly larger anode capacity as compared to the predicate device.
Similar.5.	Subject device has a smaller detector size, this affects the maximum scan view field, and does not affect the device's safety and efficacy.
Similar.6.	The pixel matrix of the detector is smaller than predicate device, 1536x1536 pixel is enough to provide high definition image, so that it does not affect the safety and efficacy of the product.
Similar.7.	Subject device has smaller pixel pitch compared to predicate device.

Overall, above difference between subject device and predicate device will not affect the device's safety and effectiveness.

7. Non-Clinical Tests Summary

The following performance testing was conducted in support of the substantial equivalence determination.

Software verification and Cybersecurity Test

Software verification and validation testing was conducted, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and " Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff ".

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing was conducted in accordance with IEC 60601-1-2:2014+A1:2020; IEC 60601-2-63:2012+A1:2017+A2:2021; IEC TS 60601-4-2:2024; IEC 60601-1:2005+A1:2012+A2:2020; IEC 60601-1-3:2008+A1:2013+A2:2021.

Biocompatibility

Biocompatibility evaluation was conducted on patient contacting accessory parts and found to be in conformance with the FDA guidance "Use of International Standard ISO 10993-1".

Performance testing - Animal

No animal study was performed to demonstrate substantial equivalence.

Bench Testing

Performance bench testing was conducted as part of design control to ensure the substantial equivalence of the predicate device. The testing was performed according to the requirements of 21 CFR Part 1020.30, 1020.31, 1020.33, DIN 6868-161, and FDA Guidance "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices". CBCT image quality, such as Line-pair resolution, Low contrast resolution, spatial resolution etc. were measured. The results demonstrate that the subject device is as safe and effective as the predicate device.

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 the sample scans and evaluated essential image quality. The overall image quality was acceptable for all cases and image types in various scanning modes for both adult and pediatric applications.

8. Conclusion

Based on the indications for use, technological characteristics, performance testing, the subject device raises no new issue of safety and effectiveness and is substantially equivalent to the predicate device.