June 4, 2026

Yofo Medical Technology Co., Ltd.
℅ Kyra Kang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Rm. 1308, Baohua International Plz.,
W. Guangzhong Rd. 555, Jingan District
SHANGHAI, CHINA

Re: K260662
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: February 27, 2026
Received: March 2, 2026

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 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

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

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.	K260662

Please provide the device trade name(s).

Dental Cone Beam Computed Tomography System

Please provide your Indications for Use below.

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).

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K260662

510(k) Summary

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
K243337	Dental Cone Beam Computed Tomography System	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: 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 the head or neck. 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, with accurate measurement, contour plots in the workstation software, supporting clinical applications in oral and maxillofacial diagnosis.

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 realize 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 for diagnostic imaging of maxillary region, mandibular region, TMJ region and other craniofacial region. The 20cm x 18cm high resolution FOV is only available in Configuration 1. 17cm x 10.5cm high resolution, 8cm x8cm Super Resolution and 4cm x4cm Super Resolution for diagnostic imaging of maxillary region and mandibular region. Under High Resolution mode, the patients will receive lower dose radiation compared to Super Resolution. The radiation dose for each scanning mode differs between pediatric and adult patients.

The following modifications have been made to the Dental Cone Beam Computed Tomography System (K243337), which primarily includes:

- Inverter Board Updates: Enhancements to component layout, power supply efficiency, and PCB routing to improve thermal performance, production quality, and system stability.
- Voice Control Board Optimization: Circuit refinements including the addition of a filter and removal of unused components to ensure signal integrity and manufacturing efficiency.
- Labeling & Component Updates: Corrections to packaging symbols and updates to power cords to comply with U.S. national difference requirements.

All indications for use and the core imaging functions of the device remain unchanged.

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	Proposed device	Predicate device (K243337)	Discussion
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 and maxillofacial areas through X-ray Cone Beam Computed Tomography (CBCT).	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).	Same
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	80kV~100kV	Same
Tube Current	2-12 mA, 2-10mA	2-12 mA, 2-10mA	Same
Target material	Tungsten	Tungsten	Same
Focal spot	0.5 mm	0.5 mm	Same
Anode capacity	49 kHU	49 kHU	Same
Detector			
Type	Amorphous Silicon	Amorphous Silicon	Same
Total Pixel Area	153.6 mm x 153.6 mm	153.6 mm x 153.6 mm	Same

Pixel Matrix	1536 x1536	1536 x1536	Same
Pixel Pitch	100µm^2	100µm^2	Same
Energy Range	40-160 kVp	40-160 kVp	Same
Gantry			
Resolution angle / Orbital angle	360°	360°	Same
Orientation	Vertical	Vertical	Same

7. Non-Clinical Tests Summary

Based on the risk analysis of the modifications above, the following verification and validation activities were performed to establish substantial equivalence:

EMC & Electrical Safety:

- IEC 60601-1 (General safety): Testing was conducted on the modified inverter board and voice control board to verify electrical safety, dielectric strength, and mechanical integrity. All tests passed with no deviations.
- IEC 60601-1-2 (Electromagnetic compatibility): EMC testing was performed to confirm that the modifications do not introduce electromagnetic interference or affect immunity. The device met all requirements.
- IEC TR 60601-4-2 (EMC/EMI guidance): Applied as guidance for test setup and risk management; no non-conformities were identified.

Performance testing:

- IEC 61223-3-7 (Constancy and acceptance testing for CBCT): Performance verification was conducted including image quality, dose repeatability, and system accuracy. Results demonstrated that the modified device performs equivalently to the predicate device.

Clinical Performance Data:

No clinical performance data is included in this submission.

8. Conclusion

The proposed device has the same intended use as the cleared predicate device (K243337). Notwithstanding the modifications described in this Summary, comprehensive risk analysis and subsequent verification and validation testing have demonstrated that these modifications do not adversely affect the safety and effectiveness of the device. Therefore, the proposed device is Substantially Equivalent to the predicate device.