June 27, 2025

Guangdong Yadeng Medical Apparatus Co., Ltd.,
% Jett Lee
Official Applicant
Guangdong Jianda Medical Technology Co., Ltd.
906 Room
Longxiang Garden, Tianhe district
GuangZhou, Guangdong 510000
CHINA

Re: K243130
Trade/Device Name: Integral Dental Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA, KLC
Dated: May 26, 2025
Received: May 27, 2025

Dear Jett Lee:

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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
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)*

K243130

Device Name

Integral Dental Unit

Indications for Use *(Describe)*

The Integral Dental Unit is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

June 23, 2025

K243130 - 510(k) Summary

1. Submitter's Information

Sponsor

- Company Name: GUANGDONG YADENG MEDICAL APPARATUS CO., LTD.
- Address: Factory 2, No.12, Fenggong Road, Nansha Industrial Zone, Danzao Town, Nanhai District, Foshan, Guangdong, 528216, P.R. China
- Phone: +86- 15916558838
- Fax: +86-0757-86603813
- Contact Person (including title): Weng changming
- E-mail: 541405168@qq.com

Application Correspondent

- Company: Guangdong Jianda Medical Technology Co., Ltd
- Address: 906 Room, Longxiang Garden, Tianhe district, Guangzhou, China
- Contact Person: Jett Lee
- Tel: 86-13512755282
- Email: jianda-lee@foxmail.com

2. Subject Device Information

- Type of 510(k) submission: Traditional
- Common Name: Unit, Operative Dental
- Trade Name: Integral Dental Unit
- Model: YD-A4
- Classification Name: Dental Operative Unit and Accessories
- Review Panel: Dental
- Product Code: EIA
- Regulation Number: 872.6640
- Regulation Class: I

3. Predicate Device Information

	Predicate Device
Sponsor	Osstem Implant Co., Ltd.
Device Name	K3

Model	/
510(k) Number	K183347

Product Code	EIA
Regulation Number	872.6640
Regulation Class	I

4. Device Description

The Integral Dental Unit (Model: YD-A4) is a dental operative unit specially designed and provided for a qualified dentist to be used in a professional clinic or hospital facility to carry out dental procedures. Integral Dental Unit is intended to be used in a professional environment for dental diagnosis, treatment, or operation.

It includes a treatment chair, dentist element, assistant element and a dental light as offering several additional options and electronically-controlled chair movements with software and water/air unit functions.

The dental unit consists of an electronically operated dental chair and integrated control unit control for electricity, water and air supply to handpieces or some other dental instrument. The device is equipped with an instrument tray, pipes for water supply and tube air supply, a mouth lamp, a saliva aspirator, a spittoon, a three-way syringe, a film viewer, a foot switch and chair with driving motors and armrest.

The dental chair is intended to be used with dental hand pieces, cure light, ultrasonic scaler, camera system or other doctor stool, which is not provided by the manufacturer. The user will select the dental instruments and accessories with FDA clearance by themself. So, the device in the submission does not include these parts and accessories. The connector standard type complies with ISO 9168.

Basic parameters/use conditions/power supply specifications is as follows:

◆Noise	＜70 dBA
◆Base box	Power supply: 115/230 Vac, 50/60Hz, single-phase 3core, protective grounding. Power input: 380 VA Water filter hole diameter: <90μm Air filter hole diameter: <25μm

◆Saliva ejector	Weak saliva: – vacuum degree **>**15 kPa; – water pumping rate＞80 mL/min Strong saliva: – vacuum degree **>**25 kPa; – water pumping rate＞1000 mL/min
◆Instrument tray	Rotating angle: >270º Up-down moving range: >440mm Max. Load: <5 Kg
◆Film viewer	Power supply: 24 V ac Inside power supply Power input: 80 VA

◆Operating light	Power supply: 12 V ac Inside power supply Power input: 50 VA Illuminance: 5 000~20 000 Lx Radiant heat: <200 W/m^2 @ max. illuminance Color rendering index: >85 Ra
◆Foot switch	Tripping force: >10N and <30N Degree of protection against harmful ingress of water: IPX4(foot switch) Service life: >25 000 repeats
◆Dental chair	Power supply: 24 V dc Inside power supply Loading capacity: 1323N (about 135 Kg) Loading capacity of headrest: 300N (about 30Kg) Moving range of headrest: 120mm Range of backrest when going backwards: 90º~170º Seat cushion's maximum height away from ground: 730mm Seat cushion's minimum height away from ground: 450mm
Attachment ----- Amalgam separation device	It has a medical device product registration card Attachment parameters are reflected in its operating instructions
◆Work space	L: ≥3 000 mm; W: ≥2 000 mm; H: ≥2 500 mm
◆Environment for operation	Temperature: +5°C to +40°C Relative humidity: 30% - 80% Atmospheric pressure: 86kPa ~ 106kPa

5. Intended Use / Indications for Use

The Integral Dental Unit is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.

6. Test Summary

The Integral Dental Unit was evaluated for conformance to recognized international standards. The following is a list of these evaluations and tests that were found to be in conformance:

- **Electrical safety test**

  IEC 60601-1:2012, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

  IEC 80601-2-60:2019, Medical electrical equipment Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- **Electromagnetic compatibility test**

  IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility
- **Biocompatibility test**

  ISO 10993-1:2018, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- **Software verification and validation test**

  FDA "Guidance for Premarket Submissions and for Software Contained in Medical Devices"
- **Software Life Cycle Processes**

  IEC 62304:2006+AMD1:2015 Medical Device Software
- **Performance Testing**

  ISO 7494-1:2018, Dentistry – Stationary dental units and dental patient chairs, Part 1: General requirements

  ISO 7494-2:2018, Dentistry – Stationary dental units and dental patient chairs, Part 2: Air, water, suction and wastewater systems

7. Comparison to predicate device and conclusion

The subject device Integral Dental Unit is substantially equivalent to the predicated device based on intended use, design, specifications and performance. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Information for predicate device was obtained from publicly available sources. A technical comparison to the predicate is provided below.

Elements of Comparison	Subject Device	Predicate Device I	Verdict
510(k) Number	K243130	K183347	--
Device Name	Integral Dental Unit (Model: YD-A4)	K3	--
Product Code	EIA	EIA	Same
Regulation Number	21 CFR 872.6640	21 CFR 872.6640	Same
Regulation Class	I	I	Same
Prescription	Prescription use	Prescription use	Same

Intended Use	The Integral Dental Unit is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.	K3 is intended to supply power to and serve as a base for dental devices and accessories. This device includes a dental chair and is intended for use in the dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.	Same
Power & Utility Supply	AC 230V, 50/60Hz, compressed air and water	AC 100-120/220-240V, 50/60Hz, compressed air and water	Similar Note 1
Main Components	Ground box, foot controller, patient chair, weak suction system, strong suction system, Triple function handpiece(hot),cuspidor: water flues&	Chair, Unit, Table, Seat, Stool, Monitor Arm*, Hanaro Console* (Note: K3 Cart* model applied ONLY)	Similar Note 1

Elements of Comparison	Subject Device	Predicate Device I	Verdict
	supply, cabinet box, operation lamp, film viewer, instrument control system, instrument tray, Triple function handpiece(cold), cup collector, glass plate		
Syringe	3-way syringe	3-way syringe	Same
Control of water and air	Uses pneumatically controlled vales to water control the flow of air and water. On/off and intensity controlled by foot pedal.	Uses pneumatically controlled vales to water control the flow of air and water. On/off and intensity controlled by foot pedal.	Same
Air Pressure	0.6MPa～0.80 MPa	500kPa(min)/750kPa(max)	Similar Note 1
Water Pressure	0.20 MPa ～0.40 MPa	250kPa(min)/600 kPa(max)	Similar Note 1
Water System	City water supply	City water supply	Same
Patient Load	Max. 135kg	Max. 135kg	Same
Chair Height	Max. 730±10mm, Min. 450±10mm	Max. 795±10mm, Min. 365±10mm	Similar Note 1
Lift Motor	Hydraulic electromotor	Hydraulic electromotor	Same
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Same
Electromagnetic compatibility	Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same

Summary for clinical test

Clinical performance testing was not performed for this device.

Conclusion

Based on the above performance as documented in this application, Integral Dental Unit is substantially equivalent to the predicate device , K3 (K183347). Thus, the subject device is substantially equivalent to the predicate devices.