May 27, 2025

Mipont Medical Equipment Co., Ltd.
Chen Salon
System Engineer
No.101, No.201, No.203, Building 1, Guangming Technology Pk
Lanhe Avenue, Lanhe, Nansha
Guangzhou, 511480
CHINA

Re: K242611
Trade/Device Name: Integral Dental Units
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA, KLC
Dated: April 8, 2025
Received: April 25, 2025

Dear Chen Salon:

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
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OHT1: Office of Ophthalmic, Anesthesia,
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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)*

K242611

Device Name

Integral Dental Units

Indications for Use *(Describe)*

The Dental Unit is intended to supply power to and serve as a base for dental devices, and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

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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"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."

K242611 - 510(k) Summary

1. Submitter's Identification:

- Company Name: Mipont Medical Equipment Co., Ltd.
- Address: No.101, No.201, No.203, Building 1, Guangming Technology Park, No. 105, Lanhe Avenue, Lanhe, Nansha, Guangzhou, China
- Phone: +86-020-39142110
- Fax: +86-020-89887711
- Contact Person (Title): Calvin Chen (General Manager)
- E-mail：official@gzfengdan.com
- Date of Preparation: May 22, 2025

2. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person (Title): Salon Chen (System engineer)
- E-mail：33999439@qq.com
- Address: Room 308, Building 11, No. 23 Jinqu Road, Wanjiang District, Dongguan City, Guangdong Province, China

3. Name of the Device:

- Name: Integral Dental Units
- Model: M100, M200, M300, M500, B100, B200, B300, B500

4. Common Name and Classification:

- Device Classification Name: Dental operative unit and accessories
- Classification Product Code: EIA

- Regulation Number: 872.6640
- Class: Class I
- Review Panel: Dental

5. Predicate Device 1 Information:

- 510(k) Number: K231845
- Device Classification Name: Dental operative unit and accessories
- Sponsor: Foshan Safety Medical Equipment Co., Ltd.
- Classification Product Code: EIA
- Regulation Number: 872.6640
- Class: Class I
- Review Panel: Dental
- Trade/Proprietary Name: Dental Unit, model: Mare

6. Predicate Device 2 Information:

- 510(k) Number: K233921
- Device Classification Name: Dental operative unit and accessories
- Sponsor: DENTIS CO., LTD.
- Classification Product Code: EIA
- Regulation Number: 872.6640
- Class: Class I
- Review Panel: Dental
- Trade/Proprietary Name: Luvis Chair (LC700C)

7. Device Description

The Integral dental unit is a dental treatment unit tested in accordance with IEC 80601-2-60.

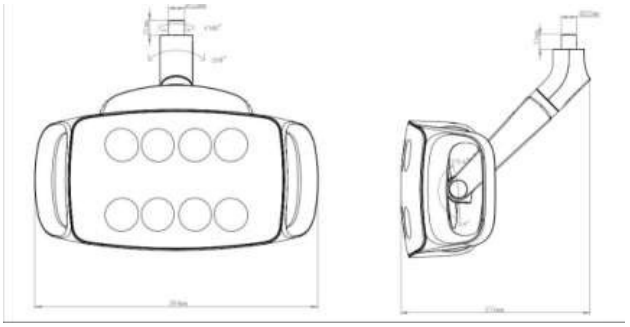
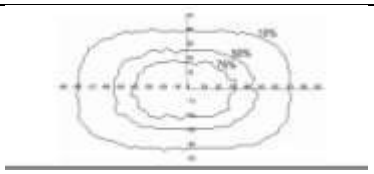
This product is used in dentistry only and may only be used by trained medical personnel and

trained professionals in the field of general dentistry. The Integral dental unit consists of a dental chair, side box, dental light, instrument tray, 3-way syringe, strong suction, weak suction, cuspidor, x-ray film viewer, and the wired foot pedal. Optional accessories include ultrasonic scalers, curing lights, dental handpieces and dental electrical motor, which are to be purchased by the user. The following accessories are recommended for use with the Integral dental unit:

Device	**510(k) Number**	**Manufacturer**
Ultrasonic Scaler	K053555	Guilin Woodpecker Medical Instrument Company, Limited
Curing Light	K243921	Foshan COXO Medical Instrument Co., Ltd.
Pneumatic Handpiece	K170229 K170236	GUANGDONG JINME MEDICAL TECHNOLOGY CO., LTD
Dental motor	K203706	Guilin Woodpecker Medical Instrument Co., Ltd.

The dental operative unit is equipped with a dental light and water heater, with specifications shown in the following tables.

Dental Light Specification	
Items	**Specification**
Weight	2.20kg
Light source	8 white light emitting diodes (LEDs) (the middle 4 white light emitting diodes (LEDs) can be switched to yellow light
illuminance	Under normal mode adjustable from < 8000 to > 40000 lux to ISO 9680 Under white and yellow mixed light mode,15000,20000,25000 lux, 3 levels adjustable, according to ISO 96680:2014
Resin safety function	Use touch switch to switch to the composite function
Color temperature	Under normal 5000K~5700K, Under white and yellow mixed light mode 4000K
Color Rendering Index (Ra)	≥90
Unit model power connection	AC 24V

Dimension of Light head, Movement and installation interface	
Illuminance diagram	

Water Heater Specification	
Items	**Specification**
Voltage and Power	AC24V 80-90W
Heating Method	Heating Coil
Storage Container Temperature	Max. 40℃
Temperature	Max. 40℃
Water Temperature:	Avg. 33 ~ 35℃
Temperature Sensor	Bi- metallic Thermostats

The dental operative unit mainly relies on electricity, compressed air, water to achieve all functions. Various ancillary dental devices can be connected to the Integral dental unit which are attached by means of industry standard ISO connections. The ancillary dental devices include 3-way syringe, strong suction and weak suction vacuum instruments are manufactured by the Mipont Medical Equipment Co., Ltd. None of the Integral dental unit parts or accessories are provided sterile.

[Note] Ancillary devices, such as dental pneumatic handpieces, are not included with this subject device. These optional device and accessories are not supplied with the subject device and are installed by the end-users using the recommended installation method described in the user manual provided by the manufacturers of these ancillary device. Also, the strong suction tip and weak suction tip are not included with the subject device and not provided with the subject device.

8. Indications for Use

The Dental Unit is intended to supply power to and serve as a base for dental devices, and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians and assistants. This product is attached with a dental chair.

9. Comparison to the predicate device

Table 1 General Comparison

Elements of Comparison	Proposed Device – K242611	Predicate Device 1 – K231845	Predicate Device 2 – K233921	Judgement
Company Name	Mipont Medical Equipment Co., Ltd.	Foshan Safety Medical Equipment Co., Ltd.	DENTIS CO., LTD.	/
Device Name	Integral Dental Units	Dental Unit, model: Mare	Luvis Chair (LC700C)	/
Regulation Description	Dental operative unit and accessories	Dental operative unit and accessories	Dental operative unit and accessories	Same
Review Panel	Dental	Dental	Dental	Same
Classification Product Code	EIA	EIA	EIA	Same
Regulation Number	872.6640	872.6640	872.6640	Same
Class	Class I	Class I	Class I	Same
Prescription or OTC	Prescription Use	Prescription Use	Prescription Use	Same
Environment of Use	Dental clinic /office environment	Dental clinic /office environment	Dental clinic /office environment	Same
Intended Use	The Dental Unit is intended to supply power to and serve as a base for dental devices, and accessories. It is intended for use in the dental clinic/office environment and used by trained dentists and/or dental	The Dental Unit is intended to supply power to and serve as a base for dental devices, and accessories. It is intended for use in the dental clinic /office environment and used by trained dentists and/or dental technicians	Luvis Chair 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	Same

	technicians and assistants. This product is attached with a dental chair.	and assistants. This product is attached with a dental chair.	dental clinic environment and is designed for use by trained dental professionals, dentists and/or dental assistants.	

Table 2 Safety factor & Performance Comparison

Safety factor & Performance		**Proposed Device - K242611**	**Predicate Device 1 – K231845**	**Predicate Device 2 – K233921**	**Judgement**
Electrical Safety		Compliance with IEC 60601-1	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Same
EMC		Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same
Usability Engineering		Compliance with IEC 62366-1	Unknown	Unknown	Note 1
Software		Compliance with IEC 62304	Compliance with IEC 62304	Compliance with IEC 62304	Same
Biocompatibility		Compliance with ISO 10993-1	Compliance with ISO 10993-1	Compliance with ISO 10993-1	Same
Features	**Operating Light**	LED	LED	Available	Same
	Connection Joint	Comply with ISO9168	Comply with ISO9168	Comply with ISO9168	Same
	Water Heating	Heating Method: Heating Coil Storage Container Temperature: Max. 40℃ Water Temperature: Avg. 33 ~ 35℃ Temperature Sensor: Bi-metallic Thermostats	No	Heating Method: Heating Coil Storage Container Temperature: Max. 40℃ Water Temperature: Avg. 33 ~ 35℃ Temperature Sensor: Bi-metallic Thermostats	Same
Operational Model		Control Panel / Assistant Control Panel / Foot Controller	Control Panel / Assistant Control Panel / Foot	/	Same

Power Supply		110V-240V	110V	100-120/220-240 V	Note 2
Frequency		50/60HZ	60Hz	50/60 Hz	Same
Power (with dental chair)		260VA	1100VA	/	Note 2
Pressure of Water Supply		200 ~ 400kPa	200kPa-400kPa	215kPa (Min) / 275kPa (Max) (2.5 ± 0.3 kgf/㎠)	Same
Pressure of Air Supply		≥550kPa	≥550 kPa	500kPa (Min) / 750kPa (Max)	Same
Dental Chair	**Loading Capacity**	150kg	150kg	Max. 150 kg	Same
	Movement Range (Chair)	380-780mm	420mm-820mm	/	Note 3
	Range of Angular Movement for Backrest	2° ~ 67°	-5° ~ 85°	0°±5° to 65°±5°	Note 3
	Movement Range (Backrest)	150mm	130mm	/	Note 3
Attached Accessories		Handpiece/ Syringe	Handpiece/ Syringe	1) Accessories: Suction (Saliva Ejector, HVE), Dry Air Syringe, 3-Way Syringe 2) Light On/Off, Cup/Spittoon Water Dispenser, Changing the Settings, Position Memories, 1 Person Helper System	Same

Rate of Water Suction	**Suction**	≥ 1L/min	≥ 1L/min	/	Same
	Saliva Ejector	> 400mL/min	> 750mL/min	/	Note 4
Performance Standards		Comply with ISO7494-1 and ISO7494-2	Comply with ISO7494-1 and ISO7494-2	Comply with ISO7494-1 and ISO7494-2	Same

Review of Differences :

Note 1

The subject device complies with the IEC 62366-1 usability requirement, whereas this information for both predicate devices is unknown. Despite this, the usability compliance ensures that the subject device is safe and effective for its intended use.

Note 2

The subject device and predicate device differ in the power supply. The subject device has demonstrated electrical safety by passing IEC 60601-1, IEC 60601-1-2, and IEC 80601-2-60 tests. Therefore, this difference does not affect the safety and effectiveness of the subject device compared to the predicate device.

Note 3

The subject device and predicate device (K231845) differ in the dental chair movement range and in range of angular movement for the backrest. The subject device has demonstrated compliance with the requirements by passing the ISO 7494-1:2018 test. Additionally, the subject device has shown electrical safety by passing IEC 60601-1, IEC 60601-1-2, and IEC 80601-2-60 tests. Therefore, this difference does not affect the safety and effectiveness of the subject device compared to the predicate device.

Note 4

The saliva ejector suction rate is > 400mL/min for the subject device, while it is > 750mL/min for the

predicate device (K231845). The subject device has demonstrated compliance with relevant electrical safety standards, including IEC 60601-1, IEC 60601-1-2, and IEC 80601-2-60. This ensures that the decreased (relative to the predicate) suction capability does not introduce any additional electrical hazards. Therefore, this difference does not affect the safety and effectiveness of the subject device compared to the predicate device.

10. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

A series of non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

1) Electrical safety

IEC60601-1:2005+A1:2012+A2:2020, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance.

ANSI AAMI ES60601-1:2005 + C1:2009 + A2:2010 + A1:2012 + A2:2021, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)].

2) Electromagnetic compatibility (EMC)

IEC 60601-1-2:2014 /AMD1:2020, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests.

IEC TR 60601-4-2:2016, Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.

3) Basic Safety and Essential Performance

IEC 60601-1-6:2010+A1:2013+A2:2020 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability.

IEC 62366-1 Edition 1.0 2015-02: Medical Devices - Application of Usability Engineering to Medical Devices.

IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the

basic safety and essential performance of dental equipment

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

ISO 7494-2:2022, Dentistry - Stationary dental units and dental patient chairs - Part 2: Air, water, suction and wastewater systems

ISO 9680:2021, Dentistry - Operating lights

4) Software Verification and Validating Testing

Software verification and validation testing were conducted and documentation was 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." The software for this device was considered as a "Moderate" level of concern.

5) Biocompatibility testing

ISO 10993-5:2019 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021 Biological evaluation of medical devices - Parts 10: Tests for skin sensitization

ISO 10993-23:2021 Biological evaluation of medical devices-Parts 10: Tests for irritation

6) Sterilization and Shelf Life & Packaging testing

ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1

ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems.

11. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

12. Conclusion

The subject devices have all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject devices. Thus, the subject devices are substantially equivalent to the predicate devices.