February 28, 2024

Foshan Safety Medical Equipment Co., Ltd
℅ You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park, No.18 Shenzhou Road,
Huangpu
Guangzhou, Guangdong 510663
CHINA

Re: K231845
Trade/Device Name: Dental Unit: model Mare
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: Class I, reserved
Product Code: EIA
Dated: January 29, 2024
Received: January 29, 2024

Dear You Yijie:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231845

Device Name

Dental unit Model: Mare

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.

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Section 5: 510(k) Summary
K231845

1. Submitter's Information

Establishment Registration Information

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Contact Person of applicant

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Contact Person of the Submission:

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Date prepared: Feb. 27, 2024

2. Device Information

Trade Name:	Dental unit
Model:	Mare
Classification name:	Dental Operative Unit & Accessories
Review panel:	Dental
Product code:	EIA
Regulation Class:	I
Regulation Number:	872.6640

3. Predicate Device Information

Primary predicate device:

510(k) submitter/holder: Zhuhai Siger Medical Equipment Co., Ltd

510(K) Number:	K142206
Trade Name:	Dental Unit
Model:	U300
Classification name:	Dental Operative Unit & Accessories
Review panel:	Dental
Product code:	EIA
Regulation Class:	I
Regulation Number:	872.6640

4. Device description

The Dental Unit(model: Mare) 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 professional in the field of general dentistry.

Dental Unit (model: Mare) consists of dental chair, arm dentist unit, assistant's unit, dental light, cuspidor, water unit, and multi-function foot control. It mainly relies on electricity, compressed air, water to achieve all functions. Various ancillary dental devices can be connected to the Dental Unit (model: Mare) which are attached by means of industry standard ISO connections. The ancillary dental devices include pneumatic handpieces, 3-way syringe, strong suction and weak suction vacuum instruments. The ancillary dental devices include 3-way syringe, strong suction and weak suction vacuum instruments are 510k clarence in the K142206. Based on Safety does not manufacture pneumatic handpieces, the pneumatic handpieces shall be purchased by the end-user. The recommended pneumatic handpieces are 510(k) clearance K170229 and K170236, which are held by GUANGDONG JINME MEDICAL TECHNOLOGY CO., LTD.
None of the Dental Unit (model: Mare), parts or accessories are provided sterile.

[Note] The ancillary device, such as dental pneumatic handpieces is not included with this subject device. These optional device and accessories are not supplied by Safety 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 by the Safety.

Principle of operation:

The dental chair is mainly composed of motors and simple mechanical equipment. During the entire operation process, the doctor can press keys on the control panel to meet their needs. The mechanical automatic control system controls the motor, which drives a worm gear device that lifts or tilts the seat as needed.

In order to make the whole process of the seat up and down activities stable, sitting and lying quiet, install the gas spring under the seat. It is a kind of spring that can save labor and take off. The gas spring is composed of a sleeve, piston and piston rod, etc., adding high pressure air or high-pressure nitrogen in the sleeve, because of the differential pressure between the two areas of the piston, to make the piston and piston rod move, support people or heavy objects.

The design of handrail takes into account that it is convenient for patients to get on and off the dental chair. The right handrail is a movable handrail. When patients get on and off the dental chair, the right handrail can be rotated clockwise to the limit position.

Headrest of Dental Unit (model: Mare) is a kind of adjustable headrest. The Adjusting the headrest can make it fit more accurately with the shape of the patient's neck and back, meeting the needs of patients with different heights. To enable the headrest to reach various positions, the design separates the headrest and back, allowing for adjustment of the height of the headrest at the upper end of the back. The headrest can be adjusted by moving the headrest slider up and down. Once adjusted to the correct height, it will automatically lock into place.

The treatment unit is composed of instrument tray, 3-way syringe, handpiece interface, strong suction and weak suction vacuum instruments., which mainly relies on water, air and electricity to achieve the treatment function.

The instrument tray of Dental Unit (model: Mare) is hanging instrument plate structure.

The 3-way syringe through the button type water/air valve to open or close water/ air. The 3-way syringes are taken and placed in line with the hanging instrument tray.

There are three handpiece interfaces on the arm of the instrument table, and it is the four-hole handpiece interfaces which meet ISO 9168. The high or low output of water/air flow from the handpiece hose is determined by the water pressure valve, diaphragm valve, and foot valve.

Foot switch is composed of main gas control valve, cooling water control valve, chip blowing valve, foot control switch, flushing, water supply switch. The main gas control valve, cooling water control valve, and chip blowing valve can switch and adjust the size of compressed air through the press-type air control valve. This enables the pressure water valve and diaphragm valve on the instrument panel to be controlled, providing necessary working conditions for handpieces and other dental devices.

Foot control switch is through four microswitches to open and close the control signal to the program controller, so as to achieve the seat lifting and pitching function. Foot control switch four microswitches are responsible for the control of the seat's rise, fall, tilt, tilt, four directions of electrical signals.

Flushing and water supply switch is through two metal button switches to send the solenoid valve electrical signals to the program controller to achieve the flushing, water supply solenoid valve open and close.

The dental unit (model: Mare) adopts integral cuspidor, mainly composed of flush nozzle, water supply nozzle and cuspidor bowl.
Flushing nozzle through the main control key, auxiliary control key, foot key switch control flushing solenoid valve switch open phlegm water to achieve flushing cuspidor bowl. By rotating the flushing nozzle direction to adjust the flushing phlegm flow direction, it is convenient to wash the stains in different directions of the cuspidor bowl.
Water supply nozzle through the main control key, auxiliary control key, foot key switch control water supply solenoid valve switch open mouthwash to realize the filling of mouthwash.
Cuspidor bowl are made of ceramic. The cuspidor bowl is connected to a drainpipe through a drainage interface to discharge mouthwash and phlegm.

The dental unit (model: Mare) adopts LED oral lamp. The LED oral lamp is mainly composed of

LED lamp bead, voltage regulator circuit board, induction switch, input power supply.
Through controlling the input power supply to realize the opening and closing of the LED oral lamp.
AC 24V power input to the oral lamp voltage control circuit board, voltage control circuit board through the rectifier, voltage control circuit for LED lamp bead to provide stable voltage and current.
The induction switch consists of an infrared emitter and an infrared receiver. By passing through the induction switch, the output power of the voltage regulator circuit can be turned on or off, achieving non-contact control over the opening and closing of the oral lamp.

5. 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.

6. Summary of technological characteristics of device compared to the predicate device (K142206)

SE Comparisons		**Subject device (Dental Unit, model: Mare)**	**Predicate device (Dental Unit, Model: U300)**	**Discussion of difference**
510K Number		/	**K142206**	**/**
Classification		21 CFR 872.6640	21 CFR 872.6640	**Same**
Product Code		EIA	EIA	**Same**
FDA Class		I	I	**Same**
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.	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.	**Same**
Model		Mare	U300	**/**
Environment of Use		Dental clinic /office environment	Dental clinic /office environment	**Same**
Features	Operating Light	LED	Halogen	**Different (Discussion is indicated in D1)**
	Connection Joint	Comply with ISO9168	Comply with ISO9168	**Same**
	Water Heating	No	Yes	**Different (Discussion is indicated in D2)**
Operation Method		Control Panel / Assistant Control Panel	Control Panel / Assistant Control Panel	**Same**

		/ Foot Controller	/ Foot Controller	
Power Supply		110V	110V	**Same**
Frequency		60Hz	50/60Hz	**(Discussion is indicated in D3)**
Power (with dental chair)		1100VA	900VA	**Different (Discussion is indicated in D3)**
Pressure of Air Supply		200kPa-400kPa	200kPa-400kPa	**Same**
Pressure of Air Supply		≥550 kPa	≥550 kPa	**Same**
Dental Chair	Loading Capacity	150kg	135kg	**Different (Discussion is indicated in D4)**
	Movement Range (Chair)	420mm-820mm	420mm-820mm	**Same**
	Range of angular movement for the backrest	-5° -85°	0° -80°	**Different (Discussion is indicated in D5)**
	Movement Range (Backrest)	130mm	200mm	**Different (Discussion is indicated in D6)**
Accessories can be attached to the device		Handpiece/ Syringe	Handpiece / Scaler / Curing Light / Syringe	**Same**

				(included by Predicate device)
Rate of Water Suction	Suction	≥ 1L/min	≥ 1L/min	**Same**
	Silva Ejector	＞750mL/min	＞750mL/min	**Same**
Performance Standards		Comply with ISO7494-1 and ISO7494-2	Comply with ISO7494-1, ISO7494-2 and ISO6875	**Same (ISO7494-1:2018 replace the ISO 6875:2011)**
Electrical Safety		Comply with IEC 60601-1	Comply with IEC 60601-1	**Same**
EMC		Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	**Same**
Patient Contact Material		Armrest: PU Leather for patient chair: PVC Syringe: Stainless steel Tube: TPU	Armrest: PU Leather for patient chair: PVC Syringe: Stainless steel Tubes: TPU	**Same**

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The subject device and predicate device have differences in oral lamp. The subject device adapted the LED oral lamp, and the predicate device used the Halogen. But the LED oral lamp of subject device has been validated for t per ISO 9680, and the subject device has demonstrated electrical safety by passing IEC 60601-1, IEC 6061-1-2 and IEC 80601-2-60 test. Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

D2: The water heating is used to generate warm water for use during dental treatment procedure, but the always be easier to form the biofilm in the waterline. The subject device lacks water heating to reduce biofilm in the waterline. The waterline biofilm treatment of subject device was performed as recommended by the manufacturer and verified according to ISO 16954, and the subject device has demonstrated electrical safety by passing IEC 60601-1, IEC 6061-1-2 and IEC 80601-2-60 test. Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

D3: The subject device has demonstrated electrical safety by passing IEC 60601-1, IEC 6061-1-2 and IEC 80601-2-60 test. Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

D4: The subject device and predicate devices have differences in dental chair loading capacity. According to the ISO 7494-1:2018, the patient chair shall support the patient mass shall be at least 150kg. The subject device has demonstrated meet the requirement by passing ISO 7494-1:2018 test and subject device has

demonstrated electrical safety by passing IEC 60601-1, IEC 6061-1-2 and IEC 80601-2-60 test. Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

D5: The subject device and predicate devices have differences in range of angular movement for the backrest. The subject device has demonstrated meet the requirement by passing ISO 7494-1:2018 test and subject device has demonstrated electrical safety by passing IEC 60601-1, IEC 6061-1-2 and IEC 80601-2-60 test. Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

D6: The subject device and predicate devices have differences in backrest movement range. The subject device has demonstrated meet the requirement by passing ISO 7494-1:2018 test and subject device has demonstrated electrical safety by passing IEC 60601-1, IEC 6061-1-2 and IEC 80601-2-60 test. Therefore, the difference will not affect the safety and effectiveness of the subject device compared to the predicate device.

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: IEC 60601-1, IEC 80601-2-60 for safety, IEC 60601-1-2 for electromagnetic compatibility, ISO 7494-1:2018, ISO 7494-2:2015, ISO 9168:2021, and ISO 9680:2021for performance, IEC 62304 for software verification and ISO 16954:2015 for waterline biofilm treatment are complied. See below table for details:

Standards	Standards Name
IEC 60601-1 Edition 3.2 2020-08	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Edition 4.0 2014-02	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 80601-2-60 Edition 2.0 2019-06	Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
ISO 7494-1 Third edition 2018-06	Dentistry - Stationary dental units and dental patient chairs - Part 1: General requirements
ISO 7494-2 Second edition 2015-04-01	Dentistry - Dental units - Part 2: Air, water, suction and waste water systems
ISO 9680:2021	Dentistry. Operating lights
ISO 17665-1 First edition 2006-08-15	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 16954:2015	Dentistry. Test methods for dental unit waterline biofilm treatment
AAMI TIR 12:2020	Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
AAMI TIR 30:2011/(R)2016	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical device
ANSI/AAMI ST79 :2017 & 2020 Amendments A1, A2, A3, A4	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ISO 9168 Third edition 2009-07-15	Dentistry - Hose connectors for air driven dental handpieces
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-10 Fourth edition 2021-11	Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23 First edition 2021-01	Biological evaluation of medical devices - Part 23: Tests for irritation
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
ASTM D4169-22	Standard Practice for Performance Testing of Shipping Containers and Systems

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.
Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
Guidance for Industry and Food and Drug Administration Staff MARCH 2015

8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Dental Unit (model: Mare) is substantially equivalent to the predicate device.