January 27, 2025

Firstar Dental Company
David Yee
Vice President
18915 East Valley Highway
Kent, Washington 98032

Re: K231297
Trade/Device Name: Firstar Dental Unit
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA
Dated: December 31, 2024
Received: January 2, 2025

Dear David Yee:

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)*

K231297

Device Name

Firstar Dental Unit

Indications for Use *(Describe)*

The Firstar Dental Unit is intended to serve as a base for ancillary dental devices and accessories by providing air, water, vacuum, and low voltage electrical power to hand-held dental instruments. The Firstar Dental Unit is intended for use by dental practitioners in a clinical environment.

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) #: K231297

510(k) Summary

Prepared on: 2024-12-31

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Firstar Dental Company
Applicant Address	18915 E Valley Highway Kent WA 98032 United States
Applicant Contact Telephone	(425) 473-6928
Applicant Contact	Mr. DAVID YEE
Applicant Contact Email	david@firstardental.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Firstar Dental Unit: 37H-DU, 38H-DU, 39H-DU, 50H-DU, 37H-DU1, 38H-DU1, 39H-DU1, 50H-DU1, 37H-DU2, 38H-DU2, 39H-DU2, 50H-DU2, 37H-DU3, 38H-DU3, 39H-DU3, 50H-DU3, SMU-A1, SMU-A2, SMU-A3, WMU-B1, WMU-B2, WMU-B3, DCU-C1, DCU-C2, DCU-C3, ASCU-D1, ASCU-D2, ASCU-D3
Common Name	Dental operative unit and accessories
Classification Name	Unit, Operative Dental
Regulation Number	872.6640
Product Code(s)	EIA

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173608	Forest Dental Operative Unit, 4485SI	EIA

Device Description Summary

21 CFR 807.92(a)(4)

The Firstar Dental Unit (also known as the delivery unit or delivery system) is a combination of dental equipment components used to carry, position, and control the devices used in the practice of dentistry. Delivery systems provide for hand pieces and other various accessories by delivering air, water, vacuum and low voltage electricity to the dentist during procedures. Depending on the configuration, it includes combinations of a Doctor Control Head (delivery head), Delivery System Foot Switch (sometimes referred to as a rheostat), Cuspidor, Side Box (Control Box), High Volume Evacuator (HVE), Saliva Ejector (SE), and an Air and Water Multifunction Syringe.

Air, water, vacuum, drainage, and electrical power utilities are delivered through the junction box via shut-off valves, pressure regulators, and electrical transformers located in the junction box or the post mounted utility box. Subsequently, internal tubing delivers the air, water and vacuum to the control head and to the dental hand pieces and multifunction syringe. Low voltage electricity is delivered to the control head for operating items such as scalers, electric hand pieces and fiber optic light sources.

The Firstar Dental Unit is available in various configurations and mounting styles including dental chair mounted, cabinet mounted, mobile cart mounted, and wall mounted. If mounted on a dental chair, the Firstar Dental Unit can be configured in two distinct styles - a pivot mounted unit which allows for ambidextrous access to the patient, and a post mounted unit which includes a side box located on one side of the dental chair that can mount a cuspidor (spittoon) on it. Despite the various applications, the key elements of the Dental Unit such as the internal plumbing, tubing, materials, power sources, utility connections, delivery head internal components, and overall operating principles remain the same.

The control head allows operators to place surgical equipment on top of the tray and it provides controls for hand piece water pressure, air pressure and electrical power. Additionally, controls for a Firstar Dental Chair are often integrated on the control head if the dental unit is configured to mount on a dental chair. If equipped, the cuspidor bowl allows 90 degrees angle rotation that provides access to collect the patient's saliva during dental treatment. The side box provides controls for the cuspidor cup fill, bowl rinse, air, and pressure regulators for the air and water quick disconnect outlets.

Various ancillary devices can be connected to the Firstar Dental Unit by means of standard ISO 9168-20 connections including but not limited to: pneumatic handpieces, electric micromotors and handpieces, air/water syringes, piezo or magnetostrictive dental scalers, curing lights, intraoral cameras, saliva ejectors, and high volume evacuators. 24VAC power supplied from the Junction Box Power Supply can be used to power electrically operated ancillary equipment such as electrical handpieces, dental scalers, etc. Firstar Dental does not manufacture the aforementioned devices except for the air/water syringes, saliva ejectors, and high volume evacuators.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Firstar Dental Unit is intended to serve as a base for ancillary dental devices and accessories by providing air, water, vacuum, and low voltage electrical power to hand-held dental instruments. The Firstar Dental Unit is intended for use by dental practitioners in a clinical environment.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are equivalent to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and predicate device share the same technical characteristics with the following differences:
- Relative humidity range
- Operating temperature range
- Air supply pressure range
- Air/oil separator
- Water supply pressure range
- Standards applied
- Syringe water flow control
- Syringe air flow control
- Maximum flex arm load

The subject device complies with relevant device standards demonstrating equivalent performance. The above differences do not raise any different questions regarding substantial equivalence compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical verification and validation tests have been performed with regards to the intended use, requirement specifications and the risk management results.The non-clinical testing was performed to demonstrate verification testing in conformance with the acceptance criteria of test methods and
recognized consensus standards shown below.

Testing was performed based on the following standards:
- 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 7494-2:2015 Dentistry — Dental units — Part 2: Air, water, suction and wastewater systems.
- ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

The test results demonstrate that the Firstar Dental Unit conforms with the relevant FDA-recognized consensus standards and guidance documents and meets the acceptance criteria. Therefore, the subject device, Firstar Dental Unit, is substantially equivalent to the predicate device.