November 3, 2025

Midmark Corporation
Rachel Schwieterman
Regulatory Affairs Specialist
60 Vista Drive
Versailles, Ohio 45380

Re: K251626
Trade/Device Name: Midmark Dental Delivery System
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit And Accessories
Regulatory Class: Class I, reserved
Product Code: EIA
Dated: October 2, 2025
Received: October 3, 2025

Dear Rachel Schwieterman:

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,
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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.	K251626

Please provide the device trade name(s).

Midmark Dental Delivery System

Please provide your Indications for Use below.

Midmark Dental Delivery Systems are intended to provide dental professionals with low voltage electric, air, and water to operate dental handpieces, syringes, and accessories during dental examinations and procedures.

Midmark Assistant's Delivery Systems are intended to provide dental professionals with air, water, and suction to operate dental handpieces, syringes, and accessories during dental examinations and procedures.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Midmark Dental Delivery System 510(k) Summary

Designing better care.™

Midmark Corporation
60 Vista Drive
Versailles, Ohio 45380
1-800-MIDMARK
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In accordance with 21 CFR §807.92, a 510(k) summary is provided below with the required information.

1. Administrative Information

Table 1. Administrative Information	
Date Summary Prepared	October 30, 2025
510(k) Sponsor Address	Midmark Corporation 60 Vista Drive Versailles, Ohio 45380
Contact Person	Rachel Schwieterman Regulatory Affairs Specialist Email: rtschwieterman@midmark.com Phone: 937-526-8567 Fax: 937-526-8482
Trade Name	Midmark Dental Delivery System
Common Name	Dental Operative Unit
Classification Name	Dental Operative Unit and Accessories (21 CFR 872.6640, Product Code EIA)
Device Classification	Class I
Review Panel	Dental
510(k) Number	K251626

2. Equivalent Predicate Comparators

Table 2. Predicate Device

Manufacturer Name	Trade Name	510(k) No.	Decision Date
Midmark Corporation	Elevance Delivery Unit	K120239	August 24, 2012

3. Indications for Use

Midmark Dental Delivery Systems are intended to provide dental professionals with low voltage electric, air, and water to operate dental handpieces, syringes, and accessories during dental examinations and procedures.

Midmark Assistant's Delivery Systems are intended to provide dental professionals with air, water, and suction to operate dental handpieces, syringes, and accessories during dental examinations and procedures.

4. Models

Table 3. Models

Model Number	Model Name
DS-1100-001	Midmark Left Right - Chair Mounted Dental Delivery System
DS-1200-001	DS-1200-CABINET Midmark 12 O'clock - Dental and Assistant's Cabinet-Mounted Delivery System
	DS-1200-COLUMN Midmark 12 O'clock Dental and Assistant's Column-Mounted Delivery System
ADS-1100-001	Midmark Chair Mounted - Assistant's Delivery System
ADS-1200-001	Midmark 12 O'clock - Cabinet Mounted- Assistant's Delivery System

5. Device Description

The Midmark Dental Delivery System encompasses two types of dental units: Dental Delivery Systems and Assistant's Delivery Systems.

The Dental Delivery System is a workstation for the dental clinical space that provides air, water and electrical power for the operation of dental instruments. The system has two models with three mounting options that can provide instrument positioning for right-handed and left-handed clinicians practicing to the patient's side or for clinicians practicing at the 12 o'clock position. The DS-1100-001 model mounts to the base of the Midmark Dental Chair. This model has a combination of swing arms and a flex arm providing both horizontal and vertical positioning of the delivery unit. The DS-1200-001 model mounts to a cabinet or column base and also includes an Assistant's Delivery System. The cabinet mount has a combination of swing arms providing horizontal positioning of the delivery unit to either side of a clinician practicing behind the patient at the 12 o'clock position. The adjustable column mount option that connects to a cabinet adds vertical positioning adjustment to the DS-1200-001.

The Dental Delivery System contains an air and water control manifold designed to route coolant air, drive air, and water to the active dental handpiece. This manifold consists of a pneumatically actuated diaphragm mechanism and an integrated air and water distribution block. When handpieces are docked in their respective instrument holders, air pressure in the handpiece line applies force to the diaphragm within the manifold, closing the associated air ports and preventing air and water flow. When a handpiece is undocked from its holder, a valve within the holder releases the air pressure against the diaphragm. When the foot control is activated, drive and coolant air pressures overcome the diaphragm, opening the previously closed air port. The foot control activation simultaneously sends a pneumatic signal to open the corresponding water valve within the manifold assembly. As a result, the drive air, coolant air, and coolant water are able to flow through the distribution pathways to the undocked handpiece. Returning the handpiece to its holder triggers the holder's valve mechanism to re-pressurize the diaphragm, re-closing the air and water distribution pathways.

The Assistant's Delivery System is a workstation for the dental clinical space that provides air, water, and vacuum for the operation of dental instruments. The ADS-1100-001 model mounts to the head end of the Midmark Dental Chair. A junction box located at the foot end of the chair base provides a contained space for the connection of the Assistant's Delivery System to air, water, and vacuum sources. The ADS-1200-001 mounts to a Midmark cabinet base. The DS-1200-001 Assistant's Delivery System mounts on a movable arm which is common to the Dental Delivery System. The Assistant's Delivery System mounts to the lower side of its supporting arm and the Dental Delivery System mounts to the upper side of the arm allowing both to pivot independently for positioning of the instruments to the clinician. The cabinetry base has a space for the connection of the Assistant's Delivery System to air, water, and vacuum sources.

Device specifications are provided in Table 4.

Table 4. Midmark Dental Delivery System Specifications

Specification	Value
Electrical Ratings	36V 5.5A
Fuse Ratings	3.15 A
Compressed Air Input	80 – 100 psig
Water Input	40 – 60 psig
Vacuum	250 Nl/min
Drive Air Output	55 Nl/min @ 45psig
Coolant Air Output	1.5 Nl/min @ 35psig
Coolant Water Output	50ml/min @ 18psig
DS-1100-001 length x width x height	59" x 19" x 36"
ADS-1100-001 length x width x height	38" x 11" x 31"
DS-1200-001 length x width x height	45" x 19" x 32"

Table 4. Midmark Dental Delivery System Specifications	
Specification	**Value**
ADS-1200-001 length x width x height	44" x 17" x 22"
DS-1100-001 Weight	76 lbs
ADS-1100-001 Weight	17 lbs
DS-1200-001 Weight	98 lbs
ADS-1200-001 Weight	43 lbs
Operating Environment	Temperature: 59 to 95°F Humidity: 10 to 90% (non-condensing) Pressure: 10 to 15.3 psi
Work Surface/Tray Size	The worksurface is inlaid with a removeable silicone rubber mat and will accommodate a 9.75" x 13.50" tray

6. Technological Characteristics

Refer to Table 5 for a comparison of the Midmark Dental Delivery System technological characteristics with those of its predicate. Changes made to the Midmark Dental Delivery System do not raise new issues of safety or effectiveness. The Intended Use of the Midmark Dental Delivery System remains identical to that of the predicate device.

Table 5. Comparison of Technological Characteristics			
Characteristic	**Subject Device: Midmark Dental Delivery System**	**Predicate Device: Elevance Delivery Units**	**Comparison**
FDA 510(k) Clearance	K251626	K120239	N/A
Product Code	EIA	EIA	Equivalent
Class	Class I	Class I	Equivalent
Regulation	872.6640	872.6640	Equivalent

Table 5. Comparison of Technological Characteristics			
Characteristic	**Subject Device: Midmark Dental Delivery System**	**Predicate Device: Elevance Delivery Units**	**Comparison**
Indications for Use	Midmark Dental Delivery Systems are intended to provide dental professionals with low voltage electric, air, and water to operate dental handpieces, syringes, and accessories during dental examinations and procedures. Midmark Assistant's Delivery Systems are intended to provide dental professionals with air, water, and suction to operate dental handpieces, syringes, and accessories during dental examinations and procedures.	The Midmark Elevance Instrument Delivery System is intended for use by professional dental practitioners in providing treatment to dental patients in a dental operatory. The system is designed to deliver air, water, vacuum and low voltage electricity to hand-held dental instruments.	Similar
Midmark Dental Delivery System Components	Doctor's instrument head and mount arms, assistant's instrument head and mount arms, air, water, and vacuum distribution, low voltage power supply	Doctor's instrument head and mount arms, assistant's instrument head and mount arms, air, water, and vacuum distribution, low voltage power supply	Equivalent
Operatory Environment	Dental Chair, Dental Light, Cuspidor, 12 o'clock Cabinet	Dental Chair, Dental Light, Cuspidor, 12 o'clock Cabinet	Equivalent
Dental Delivery System Instrument Components and Controls:			
Delivery Unit Mount Options	Midmark Dental Chair or 12 o'clock Column/Cabinet mounted swing arms	Elevance Dental Chair or 12 o'clock Cabinet mounted swing arms	Similar
Delivery Unit Height Adjustment	Spring-loaded flex arm	Spring-loaded flex arm	Equivalent
Flex Arm Release	Not required	E-field sensor and pilot air switch	Different
Delivery Unit Instrument Holders	Four or six positions are available, up to five instruments may be controlled by a pneumatic foot control	Four or six positions are available, up to five instruments may be controlled by a pneumatic foot control	Equivalent
System Master Switch	Pneumatic valve	Pneumatic valve	Equivalent

Table 5. Comparison of Technological Characteristics			
Characteristic	**Subject Device: Midmark Dental Delivery System**	**Predicate Device: Elevance Delivery Units**	**Comparison**
Instrument Detection	Pneumatic pilot valve and air actuated electronic signal	Pneumatic pilot valve and optical sensor	Similar
Instrument Air and Water Line Actuation	Midmark proprietary diaphragm module	Midmark proprietary kink valves	Different
Instrument Drive Air Volume	Manually adjustable pinch valves	Proportional solenoid valve	Different
Instrument Coolant Water Volume	Manually adjustable needle valves	Proportional solenoid valve	Different
Instrument Coolant Air Volume	Manually adjustable needle valve	Manually adjustable needle valve	Equivalent
Handpiece Line Flush	Manually actuated pilot valve	Electronic solenoid pilot valve.	Different
Syringe Air and Water Volume	Manually adjustable pinch valves	Manually adjustable needle valves	Similar
Air and Water Shutoff for Bien Air Endodontics Mode	Not available	Electronic solenoid valve	Different
Air and Water External Ports	Panel mounted couplers with automatic shutoff	Panel mounted couplers with automatic shutoff (included on the assistant's unit)	Equivalent
Foot Control	Provides variable drive air to engage and operate doctor's instruments; includes a wet/dry switch	Provides variable drive air to engage and operate doctor's instruments; includes a wet/dry switch	Equivalent
Instrument Lubrication Oil Collection System	Plastic housing with gauze	Plastic housing with gauze	Equivalent
Midmark Dental Chair and Light Remote Control	Touchpad membrane	Touchpad	Equivalent
Software Updates	Software updates via a wired CAN message from a network connected Midmark Dental Chair.	Software updates via USB on the display control PCBA	Different
USB Port	Pass-through USB extender and USB port	Pass-through USB extender and USB port	Equivalent
Dental Delivery System Instrument Options (Non-Midmark Manufactured Devices):			

Table 5. Comparison of Technological Characteristics			
Characteristic	**Subject Device: Midmark Dental Delivery System**	**Predicate Device: Elevance Delivery Units**	**Comparison**
Air-Driven Handpiece Connector Options	High-speed or low-speed handpiece connector with or without integrated illumination	High-speed or low-speed handpiece connector with or without integrated illumination	Equivalent
Bien Air Electric Motor	Not available	Single or dual system including Bien Air control module. Motor settings provided via a touchpad and display screen.	Different
Piezoelectric Scaler	Includes scaler control module with setting adjusted manually via potentiometer.	Includes scaler control module with setting provided via a touchpad and display screen.	Similar
Magneto-Strictive Scaler	Includes scaler control module with setting adjusted manually via potentiometer.	Includes scaler control module with setting provided via a touchpad and display screen.	Similar
Syringe options	3-way air and water syringe or air only syringe; accepts autoclavable or disposable tips	3-way air and water syringe or air only syringe; accepts autoclavable or disposable tips	Equivalent
Assistant's Delivery System Components and Controls:			
Assistant's Unit Mount Options	Midmark Dental Chair or 12 o'clock Cabinet/Column mounted swing arms	Elevance Dental Chair or 12 o'clock Cabinet mounted swing arms	Similar
Assistant Instrument Holders	Four holders are standard	Four holders are standard	Equivalent
Midmark Dental Chair and Light Remote Control	Touchpad membrane	Touchpad	Equivalent
Vacuum Solids Collector	Solids collector built into housing, accepts disposable baskets	Solids collector built into housing, accepts disposable baskets	Equivalent
Syringe Water and Air Controls	Manual needle valves	Manual pinch valves	Similar

Table 5. Comparison of Technological Characteristics			
Characteristic	**Subject Device: Midmark Dental Delivery System**	**Predicate Device: Elevance Delivery Units**	**Comparison**
Assistant's Delivery System Instrument Options (Non-Midmark Manufactured Devices):			
High Volume Evacuator (HVE)	HVE housing with shutoff, accepts disposable tips	HVE housing with shutoff, accepts disposable tips	Equivalent
Illuminated HVE	Zyris Isolite illuminated HVE option	Not available	Different
Saliva Ejector (SE)	SE housing with shutoff, accepts disposable tips	SE housing with shutoff, accepts disposable tips	Equivalent
Syringe Options	3-way air/water syringe or air only syringe; accepts autoclavable or disposable tips	3-way air/water syringe or air only syringe; accepts autoclavable or disposable tips	Equivalent
Air/Water/Electric Supply Components:			
Water Distribution	Self-contained water bottle system or city water regulator and shutoff valve.	Self-contained water bottle system or city water regulator and shutoff valve.	Equivalent
Air Distribution	Air regulator and shutoff valve	Air regulator and shutoff valve	Equivalent
Power Supply	36Vdc Low voltage output with 120Vac input	24Vac Low voltage output with 120Vac or 240Vac input	Similar

7. Non-Clinical Test Data

Non-clinical testing and evaluations were performed for the Midmark Dental Delivery System. The non-clinical tests demonstrated that the Midmark Dental Delivery System meets the applicable requirements of the referenced standards, and the results support that the device performs as safe and as effective as the legally marketed predicate device for its intended use.

Electrical Safety and Electromagnetic Compatibility:

The Midmark Dental Delivery System was evaluated to IEC 60601-1, ANSI/AAMI ES60601-1, IEC 60601-1-2, IEC 80601-2-60, and IEC TS 60601-4-2 to ensure compliance with electrical safety standards.

Performance Testing:

The Midmark Dental Delivery System was evaluated to ISO 7494-1, ISO 7494-2, and ISO 9168 to verify performance of the device.

Reprocessing Testing:

The Midmark Dental Delivery System had reprocessing validations conducted in accordance with the FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", issued March 17, 2015. Additional verification testing was completed on the dental unit water lines according to ISO 16954.

Software Verification:

The software of the Midmark Dental Delivery System was verified in accordance with the FDA guidance "Content of Premarket Submissions for Device Software Functions", issued June 14, 2023.

Biocompatibility:

Biocompatibility testing was completed for the Midmark Dental Delivery System utilizing ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-23.

A summary of evaluations are shown in Table 6. Based on the results of studies performed, the Midmark Dental Delivery System does not raise new issues of safety or effectiveness.

Table 6. Non-Clinical Performance Data

Standard	Standard Name
IEC 60601-1-2:2020 Ed. 4.1	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
ANSI/AAMI ES60601-1:2005+A2:2010(R2012)+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)]
IEC 60601-1:2005/A1:2012/A2:2020	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
IEC TS 60601-4-2:2024	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
ISO 7494-1:2018	Dentistry - Stationary dental units and dental patient chairs - Part 1: General requirements

Table 6. Non-Clinical Performance Data

Standard	Standard Name
ISO 7494-2:2022	Dentistry - Stationary dental units and dental patient chairs - Part 2: Air, water, suction and wastewater systems
ISO 9168:2009	Dentistry - Hose connectors for air driven dental handpieces
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
ISO 16954:2015	Dentistry — Test methods for dental unit waterline biofilm treatment

8. Clinical Performance Data

Clinical data was not required.

9. Conclusion

In terms of Intended Use, design, material, principles of operation, energy source, and performance in nonclinical testing, Midmark has determined that the subject Midmark Dental Delivery System is substantially equivalent and is as safe and effective and performs as well as or better than the legally marketed predicate device, the Elevance Delivery Unit (K120239).