



September 23, 2026

SETAGAYA SEIKI Co., Ltd.
% Akiko Dohi
Senior Regulatory Consultant
Ken Block Consulting, LLC
3400 N Central Expy., Suite 100-265
Richardson, Texas 75080

Re: K262144

Trade/Device Name: DIAMED Handpiece; DIAMED Airmotor; DIAMED Airmotor Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB, EGS
Dated: June 25, 2026
Received: June 25, 2026

Dear Akiko Dohi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

510(k) Number (if known)
K262144

Device Name
DIAMED Handpiece;
DIAMED Airmotor;
DIAMED Airmotor Handpiece

Indications for Use (Describe)

DIAMED Handpiece is intended for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations, polishing teeth, and hygiene dentistry work. All the devices are autoclavable.

DIAMED Airmotor is used to power various attachments which helps dental clinician perform various dental procedures. All the devices are autoclavable.

DIAMED Airmotor Handpiece is an air-powered dental handpiece for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations, polishing teeth, and hygiene dentistry work. All the devices are autoclavable.

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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510(k) Summary – K262144

Applicant/ Sponsor: SETAGAYA SEIKI Co., Ltd.

Contact Person: Mr. Shigehiro Sasaki
General Manager
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sasaki@setagayaseiki.co.jp

Date Prepared: September 11, 2026

Subject Device Manufacturer: SETAGAYA SEIKI Co., Ltd.
Trade Name: DIAMED Handpiece;
DIAMED Airmotor;
DIAMED Airmotor Handpiece
Classification Name: Handpiece, Air-Powered, Dental
Classification Product Code: EFB
Subsequent Product Codes: EGS
Regulation Number: 21 CFR 872.4200
Common Name: Dental Handpiece and Accessories
Class: I

Primary Predicate Device: Clearance: K073652, 03/20/2008
Manufacturer: NAKAMURA DENTAL HANDPIECE MFG. CO., LTD.
Trade Name: ND LOW SPEED AIRMOTOR AND HANDPIECE,
HIGHSPEED AIRTURBINE HANDPIECE, E-TYPE
STRAIGHT NOSECON AND CONTRA ANGLE
Classification Name: Handpiece, Air-Powered, Dental
Classification Product Code: EFB
Subsequent Product Codes: EGS
Regulation Number: 21 CFR 872.4200
Common Name: Dental Handpiece and Accessories
Class: I

Secondary Predicate Device: Clearance: K141886, 05/13/2015
Manufacturer: Modern Korea Co., Ltd
Trade Name: MDK HANDPIECES
Classification Name: Handpiece, Air-Powered, Dental
Classification Product Code: EFB
Regulation Number: 21 CFR 872.4200
Common Name: Dental Handpiece and Accessories
Class: I

Device Description The proposed devices for this submission include the DIAMED Handpiece, DIAMED Airmotor, and DIAMED Airmotor Handpiece. All proposed devices are driven by air and are intended to be used solely by well trained professionals in the field of general dentistry. The subject devices are provided non-sterile and must be cleaned and sterilized prior to first use and after each patient use.



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Indications for Use Statement DIAMED Handpiece is intended for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations, polishing teeth, and hygiene dentistry work. All the devices are autoclavable.

DIAMED Airmotor is used to power various attachments which helps dental clinician perform various dental procedures. All the devices are autoclavable.

DIAMED Airmotor Handpiece is an air-powered dental handpiece for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations, polishing teeth, and hygiene dentistry work. All the devices are autoclavable.

Summary of Technological Characteristics: The proposed device, primary predicate, and secondary predicate have similar technological features. The Indications for Use for all devices describe the same intended clinical purpose, despite minor wording differences. The indications for use statement for the proposed handpieces collectively encompass the clinical procedures represented in that of the predicate handpieces. Additional descriptive elements in the primary predicate's Indications for Use, such as power source, compatible burs, or gear ratio, do not alter the intended clinical purpose. This difference does not cause new risks. The Indications for Use statement for the proposed and primary predicate airmotors are identical.

The proposed and primary or secondary predicate devices are equivalent or similar across all key technological characteristics. All devices use the same operational mode, lack fiber optics (where applicable), and include equivalent chuck types (where applicable). Material composition was confirmed biocompatible per ISO 10993. The chuck mechanism, bur retention force, and maximum rotation speed are slightly different, and these differences were evaluated through ISO 14457 testing and shown to be as safe and as effective as the predicate devices.

Based on the similarities and the differences that were evaluated through FDA-recognized standards and determined not to introduce new risks, the proposed, primary predicate, and secondary predicate handpieces are considered substantially equivalent.

A brief summary of the regulatory and technological characteristics in comparison to those of the primary and secondary predicate devices is as follows:

	Subject Device	Primary Predicate Device	Secondary Predicate Device
	DIAMED Handpiece DIAMED Airmotor DIAMED Airmotor Handpiece	K073652 ND Low Speed Airmotor and Handpiece, Highspeed Airturbine Handpiece, E-Type Straight Nosecone and Contra Angle	K141886 MDK handpieces – Low speed handpieces
Regulatory Characteristics			
Classification Name	Handpiece, Air-Powered, Dental	Handpiece, Air-Powered, Dental	Handpiece, Air-Powered, Dental
Regulation Number	872.4200	872.4200	872.4200
Classification Product Code	EFB	EFB	EFB
Subsequent Product Code	EGS	EGS	N/A
Medical Specialty	Dental	Dental	Dental
Rx or OTC Use	Rx Only	Rx Only	Rx Only
Clinical Area	General Dentistry and Dental Hygiene	General Dentistry and Dental Hygiene	General Dentistry and Dental Hygiene
Indications for Use Statement	DIAMED Handpiece is intended for removing carious material and excess filling material, cavity and crown preparation, root canal	ND E-type contra angle is powered by either low speed airmotor or electric micromotor for removing carious material and excess filling	MDK low-speed handpieces used for teeth cutting, cavity and crown preparation, restorations and polishing teeth.



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	Subject Device	Primary Predicate Device	Secondary Predicate Device
	DIAMED Handpiece DIAMED Airmotor DIAMED Airmotor Handpiece	K073652 ND Low Speed Airmotor and Handpiece, Hightspeed Airturbine Handpiece, E-Type Straight Nosecone and Contra Angle	K141886 MDK handpieces – Low speed handpieces
	preparations, finishing tooth preparations, restorations, polishing teeth, and hygiene dentistry work. All the devices are autoclavable. DIAMED Airmotor Handpiece is an air-powered dental handpiece for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations, polishing teeth, and hygiene dentistry work. All the devices are autoclavable.	material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. EC-20L and EC-30BL are 1:1 ratio, EG-20L is 4:1 ratio, and EGG-20L is 16:1 ratio. All of the devices are autoclavable. ND u-type prophylaxis angle is used mounted on U-type nose attachment powered by either lowspeed airmotor or electric micromotor for hygiene dentistry work. All the devices are fully autoclavable. ND straight nosecone is powered by either lowspeed airmotor or electric micromotor for removing carious material and excess filling material, cavity and crown preparation, root canal preparations, finishing tooth preparations, restorations and polishing teeth. ES-30A is E-type 1:1 ratio, ESG-30AR is E-type 4:1 ratio, and MWS-30A is Midwest-type 1:1 ratio. All the devices are autoclavable. They accept 2.35mm (3/32") standard burs and can have prophy angles mounted. ND air powered low speed airmotor is used to power various U-type attachment which helps dental clinician perform the hygiene dentistry work. All the devices are autoclavable.	All the devices are designed for use by a trained professional in the field of general dentistry.
	DIAMED Airmotor is used to power various attachments which helps dental clinician perform various dental procedures. All the devices are autoclavable.	ND air powered low speed airmotor is used to power various attachment which helps dental clinician perform various dental procedures. All the devices are autoclavable.	N/A
Handpieces Technical Characteristics Comparison			
Model	DIAMED Handpiece E-type contra-angle: • DIAMED Handpiece E-type Push Button Contra Angle (Model: H5AB00, H5AB15, H5AB16, H6AB00, H6AB15, H6AB16) • DIAMED Handpiece E-type Latch Contra Angle (Model: H7AB00, H8AB00, H9AB00, H7AB15, H8AB15, H9AB15, H7AB16, H8AB16, H9AB16) DIAMED Handpiece E-type prophy contra angle: • DIAMED Handpiece E-type Prophy Contra Angle (Model: HHAB00, HHAB16, HHAB16) • DIAMED Handpiece E-type Vertical Reciprocating Contra Angle (Model: HLAB00, HLAB15, HLAB16)	ND E-type Contra Angle (Model: EC-20L, EC-30BL, EG-20L, EGG-20L) ND U-type Prophylaxis Angle (Model: RA-10PS, RA-10PK, RA-50PS, RA-50PK, DC-10L, DU-20L) ND Straight Nosecone (Model: ES-30A, ESG-30AR, MWS-30A) ND Low speed Airmotor Handpiece (Model: MD-50M, MD-50B, MD-20M, MD-20B, MP-40M)	MDK handpieces – Low speed handpieces (10 models)



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	Subject Device	Primary Predicate Device	Secondary Predicate Device
	DIAMED Handpiece DIAMED Airmotor DIAMED Airmotor Handpiece	K073652 ND Low Speed Airmotor and Handpiece, Highspeed Airturbine Handpiece, E-Type Straight Nosecone and Contra Angle	K141886 MDK handpieces – Low speed handpieces
	DIAMED Handpiece E-type Straight nose cone (Model: S0A) DIAMED Airmotor Handpiece (Model: M4A, MBA, SCAMCA)		
Operational Mode	Air driven	Electric or air driven	Air driven
Fiber optics	No	No	With or without built-in light system
Type of chuck	Push-button, latch-type, screw-in, tip-lock, and mechanical (bur-lock-ring) chuck options	Information not available	Push button, latch, screw, snap-on or tip-lock chuck options
Composition of materials	Brass, Bronze, Aluminum, Stainless Steel, chrome-plating, nickel-plating	Information not available	Stainless steel and titanium
Bur retention force	32N	Information not available	30N
Maximum rotation speed	Up to 40,000 rpm	Up to 30,000 rpm	Up to 20,000 rpm
Accessories	Head opener (Head Cap Wrench): H5AB00, H5AB15, H5AB16, H6AB00, H6AB15, H6AB16 Head opener (Cap Wrench) : H7AB00, H8AB00, H9AB00, H7AB15, H8AB15, H9AB15, H7AB16, H8AB16, H9AB16 Connector for inserting lubricant (E-type Spray Nozzle): H5AB00, H5AB15, H5AB16, H6AB00, H6AB15, H6AB16, H7AB00, H8AB00, H9AB00, H7AB15, H8AB15, H9AB15, H7AB16, H8AB16, H9AB16	Information not available	Head opener for the latch type, Connector for inserting lubricant, External Spray Tubing with nozzle
Lubricant	NSA PANA-SPRAY Plus (K163483)	Lubricant oil (product name not specified)	Pana-Spray (K052700)
Sterilization	Steam autoclave method	Steam autoclave method	Steam autoclave method
Airmotor Technical Characteristics Comparison			
Model	DIAMED Airmotor (Model: M0A, M2A, M3A, M8A)	ND Low Speed Airmotor (Model: ME-20M, ME-20B, ME-80M, ME- 80B)	N/A
Operational Mode	Air driven	Air driven	
Max Air Consumption	Less 66NL/min	Information not available	
Hose Connection Type	ISO 9168 Type 1 and 2	Information not available	
Coupling Type	ISO 3964 Type E	Information not available	
Composition of materials (Airmotor)	Aluminum, stainless steel, bronze	Information not available	
Composition of materials (Waterpipe)	Brass, nickel-plating	Information not available	
Operating pressure	0.25MPa	0.2MPa	
Maximum rotation speed	25,000 rpm	5,000 rpm: ME-80M, ME-80B 20,000rpm: ME-20M, ME-20B	
Spray Air Supply	N/A: M0A 1.5NL/min: M2A, M3A, M8A	Information not available	
Water Supply	N/A: M0A 50mL/min: M2A, M3A, M8A	Information not available	
Accessories	N/A	Information not available	
Lubricant	NSA PANA-SPRAY Plus (K163483)	Lubricant oil (product name not specified)	
Sterilization	Steam autoclave method	Steam autoclave method	



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Summary of Non-Clinical/ Test Data:

A series of non-clinical tests were conducted to verify that the proposed devices meet all design specifications and are substantially equivalent to the predicate devices, in accordance with FDA-recognized standards and applicable FDA guidance documents.

Biocompatibility was evaluated in accordance with ISO 10993, including the following parts:

- 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*

Reprocessing was validated in accordance with:

- FDA guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*,
- AAMI/ANSI/ISO 17665-1:2006 *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

Performance testing was conducted in conformance with ISO 14457:2017, *Dentistry—Handpieces and Motors*.

Clinical Testing:

No clinical testing was required as non-clinical testing should be sufficient to demonstrate that the proposed device works as intended.

Conclusion:

Setagaya Seiki Co., Ltd. considers the proposed device to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in application/intended use, principles of operation, functional design, and established medical use.