



January 30, 2026

Saeshin Precision Co., Ltd.
% Sanghwa Myung
Regulatory Affair Specialist
E&M
D1474, PyeongCheon Arco Tower, 230, Simin-Daro, Dongan-gu
Anyangsi, Gyeonggido 14067
SOUTH KOREA

Re: K251407

Trade/Device Name: Motor Handpiece and Control Unit (SDI10)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: December 29, 2025
Received: December 29, 2025

Dear Sanghwa Myung:

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

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.

K251407

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Please provide the device trade name(s).

?

Motor Handpiece and Control Unit (SDI10)

Please provide your Indications for Use below.

?

SDI10 is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.

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)

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510(k) Summary

K251407

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Date 510(k) summary prepared: January 29, 2026

Common Name: Motor Handpiece and Control Unit
Trade Name: Motor Handpiece and Control Unit (SDI10)
Classification: I
Product Code: EBW
Classification Panel: Dental
Regulation Numbers: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories

Description of Device:

SDI10 can be connected to a handpiece and a dental unit chair. This device is a LED Optic attachment sensorless micro motor system that can be connected and used with a dental unit (air unit). It consists of a control unit, micro-motor and AC/DC adapter.

Indication for use:

SDI10 is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.

Predicate Device:

Manufacturer: MICRO-NX Co., Ltd.
 510(k) Number: K201191
 Trade/Device Name: 21 CFR 872.4200
 Regulation Name: Dental handpiece and accessories
 Regulatory Class: Class I
 Product Code: EBW

Substantial Equivalence: Comparison table is as follows.

Table 1: Substantial equivalence comparison

1) Predicate Device

Descriptive Information	Subject Device	Predicate Device	Comparison Comment
Manufacturer	Saeshin Precision Co., Ltd.	MICRO-NX Co., Ltd.	-
Device Name	SDI10	ELEC-LED (EL-B40S, EL-B40L, EL-B40M, EL-B40I)	-
510(k) number	K251407	K201191	-
Classification Product Code / Regulatory Number	EBW	EBW	-
Regulatory Class	Class I	Class I	-
Indications for Use	SDI10 is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.	The ELEC-LED is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.	Same
Type of motor	Brushless, internal coolant air	Brushless, internal coolant air	Same
Device components	Control unit with hose and electrical motor	Control unit with hose and electrical motor	Same
Power supply voltage	DC 40V	AC 24V	Different #1
Speed	2,000 – 40,000 rpm	1,000-40,000 rpm	Substantially Equivalent
Max. Torque	3Ncm	3Ncm	Same

Rotation direction	clockwise / counterclockwise	clockwise / counterclockwise	Same
Spray Air Pressure	2.5bar	2.5bar	Same
Spray Water Pressure	2bar	2bar	Same
Irrigation system	Yes	1) EL-B40S, EL- B40S, EL-B40I (Irrigation system, motor cooling air) 2) EL-B40M (only motor cooling air)	Substantially Equivalent
Light (Motor LED)	Yes	1) Yes (EL-B40S, EL-B40L) 2) No (EL-B40I, EL-B40M)	Substantially Equivalent
Conformance with standards for shanks	Comply with ISO 3964	Comply with ISO 3964	Same
Rotation	Clockwise, Counterclockwise	Clockwise, Counterclockwise	Same

Differences between Subject and Predicate Device

Different #1 Power supply voltage

The input voltage of the subject device is DC 40V, while the input voltage of predicate device is AC 24V. The device safety and performance test were conducted according to IEC 60601-1 and IEC 60601-1-2. The differences do not raise different questions of safety and effectiveness.

Discussion

The subject device is substantially equivalent to the predicate device with respect to indications for use, type of motor, device components, speed, max torque, rotation direction, spray air and water pressure.

Biocompatibility:

Biocompatibility testing (cytotoxicity, sensitization, irritation) was conducted on the direct and indirect tissue contacting components in accordance with ISO 10993-1. The device materials have been confirmed to be biologically safe.

- 1) ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 2) ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- 3) ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- 4) ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- 5) ISO 10993 -23 Biological evaluation of medical devices – Part 23: Tests for irritation
- 6) Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Non-clinical Performance Data:

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices
- IEC 60601-1-2 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 Medical electrical equipment – Part 2-60: Particular Requirements for The Basic Safety and Essential Performance of Dental Equipment
- ISO 14457 Dentistry – Handpieces and motors
- ISO 17665-1 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 17664-1 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices
- ISO 17664-2 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices
- Cleaning, Sterilization, and Disinfection validation was provided per the FDA guidance document, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”
- Electromagnetic Compatibility testing and labeling was provided per the FDA guidance document, “Electromagnetic Compatibility (EMC) of Medical Devices”
- Software documentation was prepared per the FDA guidance document, “Content of Premarket Submissions for Device Software Functions”
- Use of International Standard ISO 10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”

Clinical Data: No clinical performance testing was performed.

Conclusion

The performance of SDI10 meets the requirements of the non-clinical bench testing conducted to support substantial equivalence. The subject device and the predicate device have the same indications for use, and similar operational principal, performance data. We conclude that the subject device is substantially equivalent to the predicate device.