September 19, 2025

NAKANISHI INC.
Saito Kaori
Regulatory Affairs Dept.
700 Shimohinata
Kanuma, Tochigi 322-8666
JAPAN

Re: K251689
Trade/Device Name: VARIOS 170 LUX SCALER SYSTEM (VA170LUXS10); VARIOS 170 LUX SCALER SYSTEM (VA170LUXS11); VARIOS 170 SCALER SYSTEM (VA170S11)
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: August 21, 2025
Received: August 21, 2025

Dear Saito Kaori:

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.	K251689

Please provide the device trade name(s).

VARIOS 170 LUX SCALER SYSTEM (VA170LUXS10);
VARIOS 170 LUX SCALER SYSTEM (VA170LUXS11);
VARIOS 170 SCALER SYSTEM (VA170S11)

Please provide your Indications for Use below.

This device, VARIOS 170 LUX SCALER SYSTEM / VARIOS 170 SCALER SYSTEM, an electronic ultrasonic scaler, is intended for use with an appropriate tip for following use: Scaling, Perio, Implant Maintenance, Endodontic, Retrograde Endo, Restorative (for Minimal Intervention/Finishing/Trimming/ Polishing/Caries of Dentin), Prosthetics (Condensation/Loosening/Plugging).

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)

510(k) #: K251689

510(k) Summary

Prepared on: 2025-09-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NAKANISHI INC.
Applicant Address	700 Shimohinata Kanuma Tochigi 322-8666 Japan
Applicant Contact Telephone	+81-289-64-7277
Applicant Contact	Mr. Kikuchi Masaaki
Applicant Contact Email	m-kikuchi@nsk-nakanishi.co.jp
Correspondent Name	NAKANISHI INC.
Correspondent Address	700 Shimohinata Kanuma Tochigi 322-8666 Japan
Correspondent Contact Telephone	+81-358-28-8590
Correspondent Contact	Ms. Saito Kaori
Correspondent Contact Email	nskra-contact@nsk-nakanishi.co.jp

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VARIOS 170 LUX SCALER SYSTEM (VA170LUXS10); VARIOS 170 LUX SCALER SYSTEM (VA170LUXS11); VARIOS 170 SCALER SYSTEM (VA170S11)
Common Name	Ultrasonic scaler
Classification Name	Scaler, Ultrasonic
Regulation Number	872.4850
Product Code(s)	ELC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K113530	Varios 970 / Varios 970 Lux	ELC
K233922	SP NEWTRON CAN-A	ELC

Device Description Summary

21 CFR 807.92(a)(4)

This device, the VARIOS 170 LUX SCALER SYSTEM / VARIOS 170 SCALER SYSTEM is an ultrasonic scaler system intended for use with an appropriate tip for the following use: Scaling, Perio, Implant Maintenance, Endodontic, Retrograde Endo, Restorative (for Minimal Intervention/Finishing/Trimming/Polishing/Caries of Dentin), Prosthetics (Condensation/Loosening/Plugging). The device consists of the VA170 Built-in Module, Ultrasonic Handpiece, Handpiece Cord, and accessories. Components and accessories are included with each series set in accordance with the client's specific needs and requirements. The device converts an ultrasonic-frequency electrical signal into mechanical vibrations using a piezoelectric ceramic, which then vibrates the tip at ultrasonic frequencies. The Tip attached at the

distal end of the transducer vibrates at ultrasonic frequencies and enables the device to achieve the intended use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This device, VARIOS 170 LUX SCALER SYSTEM / VARIOS 170 SCALER SYSTEM, an electronic ultrasonic scaler, is intended for use with an appropriate tip for following use: Scaling, Perio, Implant Maintenance, Endodontic, Retrograde Endo, Restorative (for Minimal Intervention/Finishing/Trimming/Polishing/Caries of Dentin), Prosthetics (Condensation/Loosening/Plugging).

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the Indications for Use for the subject device and the Indications for Use for the predicate device are intended for scaling, endodontics, and periodontics in dental treatments. The only difference between the Indications for Use is the Device Name and product description.

Technological Comparison

21 CFR 807.92(a)(6)

The subject control unit is an ultrasonic therapy device designed to be embedded into a dental delivery system. This feature is not present in the predicate device but is included in the reference device.

The subject ultrasonic handpiece is a device that is connected to a dental ultrasound treatment device and has the same functionality as the predicate device, but the type of material in biological contact is different.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Tests
The following non-clinical tests were performed to support substantial equivalence of the subject device.

Performance Test:
The subject instrument was subjected to verification and validation testing for powered scaler performance, reprocessing, software, electrical safety, EMC, and cybersecurity to support substantial equivalence. The results of these tests demonstrate compliance with the requirements of the following standards and guidance.

- ISO 18397:2016 "Dentistry - Powered scaler "
- 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"
- ISO 17664-1:2021 "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 17664-2:2021 "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."
- IEC 62304:2006+AMD1:2015 "Medical device software - Software life cycle processes"
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- IEC 60601-1-2:2014+AMD1:2020 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- IEC 81001-5-1:2021 "Health software and health IT systems safety, effectiveness and security - Part 5-1:Security - Activities in the product life cycle"
- FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"
- FDA guidance document "Content of Premarket Submissions for Device Software Functions"
- FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"

Biocompatibility Test:
Based on its Indications for Use, the subject device, the ultrasonic handpiece, is classified as a device that has limited contact (less than 24 hours) with externally communicating medical devices and tissue / bone / dentin.
To support substantial equivalence, biocompatibility testing was conducted. The test results demonstrate compliance with the requirements of the following standards and guidance:
- ISO 10993-1:2018 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- FDA guidance document "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

Clinical Tests
N/A

Nonclinical tests concluded that the device is as safe, as effective, and performs as well as its predicates.