March 10, 2026

Nakanishi, Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K260773
Trade/Device Name: Varios Combi Pro2
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic scaler
Regulatory Class: Class II
Product Code: ELC, KOJ
Dated: March 9, 2026
Received: March 9, 2026

Dear Prithul Bom:

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.	K260773

Please provide the device trade name(s).

Varios Combi Pro2

Please provide your Indications for Use below.

The dental device is intended for the following application(s):
[Tooth Polishing System]
Removal of supragingival and subgingival accretions and deposits, and accretions and deposits on prostheses (including
implants).
[Ultrasonic Scalers]
Removal of accretions and deposits from the surface of teeth and dental restorations (fillings and prostheses), finishing
(preparation and adjustment/polishing), removal and cleaning of infected dental tissues, and root canal preparation.

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

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

510(k) #: K260773

510(k) Summary

Prepared on: 2026-03-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NAKANISHIINC.
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Correspondent Contact	Ms. Kim Junghee
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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Varios Combi Pro2 (Varios Combi Pro2 Basic Set)
Common Name	Ultrasonic scaler
Classification Name	Scaler, Ultrasonic
Regulation Number	872.4850
Product Code(s)	ELC, KOJ, EJR

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K190124	EMS AIRFLOW Prophylaxis Master, EMS AIRFLOW One	ELC

Device Description Summary

21 CFR 807.92(a)(4)

Varios Combi Pro2 consists of the control unit, the foot control, the ultrasonic handpiece, the powder handpiece, and accessories. The control unit integrates two operational systems: an ultrasonic generator for scaling and a powder supply system for air polishing. It is used to control functions such as power output, irrigation flow, powder/air mixture, and operation mode. The foot control allows for "hands-free" control of the spray, power output, and turning the device on/off. The ultrasonic handpiece (VA2-LUX-HP Ti) incorporates a piezoelectric transducer that converts the electrical signal into mechanical vibrations and is also equipped with LED illumination. The powder handpiece directs a mixture of powder, air, and water to the tooth surface for cleaning.

Varios Combi Pro2 is intended for use in dental periodontal therapy and tooth surface cleaning for procedures such as scaling, root canal preparation, and the removal of stains and plaque. The device is designed to be used with the ultrasonic handpiece for removing hard deposits and with the powder handpiece for removing supragingival and subgingival accretions, deposits, and stains from teeth and prostheses.

A feature of this product is the integration of ultrasonic scaling and powder polishing capabilities into a single unit, allowing for efficient workflow in oral hygiene management. The system automatically detects the attached chamber (Prophy or Perio) to select the appropriate powder operating mode. It also features Bluetooth connectivity with the foot control for wireless operation.

The product is supplied non-sterile. The handpieces, tips, and nozzles are to be cleaned and sterilized at a medical facility before use and are intended for repeated use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The dental device is intended for the following application(s):
[Tooth Polishing System]
Removal of supragingival and subgingival accretions and deposits, and accretions and deposits on prostheses (including implants).
[Ultrasonic Scalers]
Removal of accretions and deposits from the surface of teeth and dental restorations (fillings and prostheses), finishing (preparation and adjustment/polishing), removal and cleaning of infected dental tissues, and root canal preparation.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use of the Tooth Polishing System falls under the intended uses of the predicate device, which include the removal of accretions, deposits, and stains; cleaning of implant fixtures and prior to bonding of orthodontic appliances; and surface preparation.

The intended use of the Ultrasonic Scalers falls under the intended uses of the predicate device, which include the removal of supragingival and subgingival accretions, deposits, and stains; scaling; root planing; root canal preparation, cleaning, and irrigation; retrograde preparation; and cavity preparation.

Therefore, this does not constitute a new intended use.

Technological Comparison

21 CFR 807.92(a)(6)

The Varios Combi Pro2 is a combined oral hygiene system driven by an AC power source, which supplies power to and controls the functions of compatible ultrasonic and powder handpieces. Its operating principle is identical to that of the Predicate device (K190124), wherein an electrical signal from the generator is converted into mechanical vibrations by a piezo transducer for scaling, and compressed air is used to spray a powder mixture for tooth polishing. This fundamental technology, as well as functions such as controlling ultrasonic output, powder spray, and irrigation volume, are shared with the Predicate device.

On the other hand, the subject device differs from the Predicate device in several aspects, including the output specifications, specific patient contacting materials, the adoption of a touch panel display for flow control, and the connection method for the wireless foot control. These modifications reflect user convenience and market strategy and do not alter the intended use or the fundamental scientific technology. It has been confirmed through compliance with relevant standards (such as IEC 60601-1, ISO 18397, and ISO 10993) and comparison with the Predicate device that these changes do not raise new questions of safety or effectiveness. Therefore, these minor differences do not affect the substantial equivalence of the device.

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 device, Varios Combi Pro2, was subjected to verification and validation testing for ultrasonic scaler and air-polishing 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 First edition 2016-01, Dentistry - Powered scaler
- ISO 20608 First edition 2018-04, Dentistry - Powder jet handpieces and powders
- 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 First edition 2021-02, 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.
- ISO 17665-1 First edition 2006-08-15, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes

• IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
• IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, 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 Edition 2.0 2019-06, Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
• IEC 81001-5-1 Edition 1.0 2021-12, 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 patient-contacting components of the subject device, specifically the Ultrasonic Handpiece and Powder Handpiece, are classified as externally communicating devices with limited contact (less than 24 hours) with tissue, bone, and dentin. To support substantial equivalence, biocompatibility testing was conducted using the final finished device (or representative samples). The test results demonstrate compliance with the requirements of the following standards and guidance:

• ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
• FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

N/A

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