September 20, 2024

Nakanishi Inc.
Ikeda Satoru
Regulatory Affairs Dept.
Tix Tower Ueno 9F
4-8-1, Higashiueno
Taito-ku, Tokyo 110-0015
Japan

Re: K241880
Trade/Device Name: Air Powered Tooth Polishing System (Perio-Mate); Air Powered Tooth Polishing System (Perio Mate Nozzle Tip)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: June 28, 2024
Received: June 28, 2024

Dear Ikeda Satoru:

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,

For 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241880

Device Name

Air Powered Tooth Polishing System (Perio-Mate);
Air Powered Tooth Polishing System (Perio Mate Nozzle Tip)

Indications for Use *(Describe)*

Perio-Mate:
Perio-Mate is intended for the following application(s):
Removal of supragingival/subgingival soft deposits and soft deposits on prostheses (including implant abutments).

Perio Mate Nozzle Tip:
Perio Mate Nozzle Tip is intended for the following application(s):
Removal of subgingival soft deposits and soft deposits on prostheses (including implant abutments).

The Perio Mate Nozzle Tip and Perio-Mate is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K241880

510(k) Summary

Prepared on: 2024-09-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	NAKANISHI INC.
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Correspondent Contact Telephone	+81-358-28-8590
Correspondent Contact	Mr. Ikeda Satoru
Correspondent Contact Email	nskra-contact@nsk-nakanishi.co.jp

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Air Powered Tooth Polishing System (Perio-Mate); Air Powered Tooth Polishing System (Perio Mate Nozzle Tip)
Common Name	Dental handpiece and accessories
Classification Name	Handpiece, Air-Powered, Dental
Regulation Number	872.4200
Product Code(s)	EFB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151912	AIR-FLOW handy 3.0 PLUS	EFB
K171174	PERIO-FLOW nozzle	EFB

Device Description Summary

21 CFR 807.92(a)(4)

Perio-Mate
This device is used to remove stains and deposits by spraying the polishing powder and water mixed by compressed air when connected with chair units through couplings and hoses to the treatment area. This device consists of a handpiece and a powder case. Couplings connected with powder case of this device have different structures, depending on manufactures. This device is developed, considering the connection with each manufacture's type. Some of them have the direct connection with hose that is with accordance with ISO 9186. This device is delivered in a non-sterile state and intended to be cleaned and sterilized by end-users as a reusable device. This device to be used for sub and supraginvival purpose. During subgingival treatment, Perio Mate Nozzle Tip is connected to the tip of

the handpiece.

Perio Mate Nozzle Tip
This device is connected to the end of the Perio-Mate handpiece. The compressed air makes the tooth polishing agent in the Perio-Mate mixed and transfers it to the tip. The product is inserted in a periodontal pocket, sprays the tooth polishing agent/water to the treatment area in the subgingival area, and enables to remove the deposits from teeth surface or prostheses. The product is EOG sterile single-use device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Perio-Mate:
Perio-Mate is intended for the following application(s):
Removal of supragingival/subgingival soft deposits and soft deposits on prostheses (including implant abutments).

Perio Mate Nozzle Tip:
Perio Mate Nozzle Tip is intended for the following application(s):
Removal of subgingival soft deposits and soft deposits on prostheses (including implant abutments).

The Perio Mate Nozzle Tip and Perio-Mate is indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm after initial periodontal treatment.

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 dental applications, including the removal of subgingival/supragingival soft deposits and soft deposits on prostheses (including implant abutments).
The subject, predicate and reference device are indicated for the non-surgical removal of subgingival plaque in pockets up to 5 mm.
The only difference between the Indictments for Use is the Device Name and product description.

Technological Comparison

21 CFR 807.92(a)(6)

The Air Powered Tooth Polishing System includes the Perio-Mate, which consists of a handpiece and a powder case, and the Perio Mate Nozzle Tip, which is connected to the end of the Perio-Mate handpiece.
Perio-Mate is used to remove stains and deposits by spraying the polishing powder and water mixed by compressed air when connected with chair units through couplings or hoses to the treatment area. This device is delivered in a non-sterile state and intended to be cleaned and sterilized by end-users as a reusable device. This device to be used for supragingival and subgingival purpose.
During subgingival treatment, Perio Mate Nozzle Tip is connected to the tip of the handpiece. The compressed air makes the tooth polishing agent in the Perio-Mate mixed and transfers it to the tip. The product is inserted in a periodontal pocket, sprays the tooth polishing agent/water to the treatment area in the subgingival area, and enables to remove the deposits from teeth surface or prostheses.
The subject device shares these technical characteristics with the predicate device. These differences are only minor, such as the Perio Mate Nozzle Tip being an EOG sterilized, disposable device, and dimensions. The Perio Mate Nozzle Tip being EOG sterilized, disposable, features that are not present in the predicate device but are present in the reference device. These differences reflect user preferences and market strategies and do not affect the substantial equivalence of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Tests
For Air Powered Tooth Polishing System, the following non-clinical tests were performed to support substantial equivalence of the subject device.
Performance Test:
The Air Powered Tooth Polishing System subject device was subjected to verification and validation testing for product performance and reprocessing to support substantial equivalence. The results of these tests demonstrate compliance with the requirements of the following standards and guidance.

- ISO 20608:2018 "Dentistry - Powder jet handpieces and powders"
- 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."

- FDA guidance document "Dental Handpieces - Premarket Notification [510(k)] Submissions"
- FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"

Biocompatibility Test:

Based on its Indications for Use, the subject device, the Air Powered Tooth Polishing System, is classified as a device that has limited contact (less than 24 hours) with surface medical devices and breached or compromised surfaces.

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 process"

The Non-Clinical Tests result support the substantial equivalence of the subject Air Powered Tooth Polishing System to the predicate device.