June 21, 2022

NAKANISHI INC.
% Kelby Villarreal
Biomedical Engineer
Ken Block Consulting LLC
800 East Campbell Road, Suite 202
Richardson, Texas 75081

Re: K203791
Trade/Device Name: Stainless Turbine
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: May 20, 2022
Received: May 23, 2022

Dear Kelby Villarreal:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.ChE.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K203791

Device Name
Stainless Turbine

Indications for Use *(Describe)*
The Stainless Turbine is intended for the following applications:
Caries removal, Cavity and crown preparation, Removal of dental restorations (fillings and prostheses), Finishing of teeth and dental restorations (preparation/adjustment).

The coupling is intended for the following applications:
A connection device to transfer energy (air, water, light) required for handpieces.

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** **K203791**


| | | |
|---|---|---|
| Submitter: | NAKANISHI INC.<br>700 Shimohinata<br>Kanuma Tochigi 322-8666 Japan | |
| Contact Person: | Mr. Masaaki Kikuchi<br>General Manager, Regulatory Affairs Dept.<br>TEL: +81-289-64-7277<br>FAX: +81-289-62-9738<br>m-kikuchi@nsk-nakanishi.co.jp | |


| | | |
|---|---|---|
| Date Prepared: | June 17, 2022 | |
| Submission Type: | Traditional 510(k) | |
| Subject Device: | Clearance: | K203791 |
| | Manufacturer: | NAKANISHI INC. |
| | Trade Name: | Stainless Turbine |
| | Common Name: | Handpiece, Air-Powered, Dental |
| | Regulatory Class: | Class I |
| | Classification Name: | Dental handpiece and accessories |
| | Product Code: | EFB |
| | Regulation: | 872.4200 |
| Primary Predicate Device: | Clearance: | K131319 |
| | Manufacturer: | Sirona Dental Systems GmbH |
| | Trade Name: | T1 / T2 / T3 Turbine family with serial no. > 600,000 |
| | Common Name: | Handpiece, Air-Powered, Dental |
| | Regulatory Class: | Class I |
| | Classification Name: | Dental handpiece and accessories |
| | Product Code: | EFB |
| | Regulation: | 872.4200 |
| Secondary Predicate Device: | Clearance: | K112024 |
| | Manufacturer: | NAKANISHI INC. |
| | Trade Name: | Ti-Max X450 |
| | Common Name: | Handpiece, Air-Powered, Dental |
| | Regulatory Class: | Class I |
| | Classification Name: | Dental handpiece and accessories |
| | Product Code: | EFB |
| | Regulation: | 872.4200 |

**510(k) SUMMARY** **K203791**

| | | |
|---|---|---|
| Reference Device: | Clearance: | K980162 |
| | Manufacturer: | NAKANISHI INC. |
| | Trade Name: | Mach-Sigma Handpiece, Ultrapush |
| | Common Name: | Handpiece, Air-Powered, Dental |
| | Regulatory Class: | Class I |
| | Classification Name: | Dental handpiece and accessories |
| | Product Code: | EFB |
| | Regulation: | 872.4200 |
| Reference Device: | Clearance: | K991701 |
| | Manufacturer: | NAKANISHI INC. |
| | Trade Name: | Mach-Sigma Handpiece, Ultrapush, Models Mach-Sigma MU (Minihead), Mach-Sigma SU (Standard Head), Mach-Sigma TU (Torque Head) |
| | Common Name: | Handpiece, Air-Powered, Dental |
| | Regulatory Class: | Class I |
| | Classification Name: | Dental handpiece and accessories |
| | Product Code: | EFB |
| | Regulation: | 872.4200 |

Device Description:

The *Stainless Turbine* handpieces are air driven dental handpieces for use by a trained professional in the field of general dentistry. The handpieces are air-powered, high-speed dental handpieces capable of reaching rotational speeds of 325,000 to 450,000 revolutions per minute. Handpiece models include fiber optic, LED, and non-optic lighting. The handpiece models are available to connect directly to NAKANISHI INC. manufactured couplings. Available handpiece models include the S-Max M Series, Pana-Max Plus Series, Pana-Max Plus2 Series, and the S-Max pico Series. The *Stainless Turbine* couplings are connection devices used to attach the dental unit to the *Stainless Turbine* handpieces. Available coupling models include the Glass Fiber Rod Series, LED Series, and No Light Irradiation Series.

Indications for Use:

The *Stainless Turbine* is intended for the following applications: Caries removal, Cavity and crown preparation, Removal of dental restorations (fillings and prostheses), Finishing of teeth and dental restorations (preparation/adjustment).

The coupling is intended for the following applications: A connection device to transfer energy (air, water, light) required for handpieces.

Summary of Technological Characteristics:

The *Stainless Turbine* handpieces are intended for use with a friction grip bur that conforms to ISO 1797-1 standard. The handpieces are capable of achieving rotational speeds of 325,000 to 450,000 revolutions per minute when provided with a supply air pressure of 0.18 to 0.30 MPa. This provides a torque of at least 0.05 N·cm, while

generating a noise level of 80 dBA or less. All models include an air-water spray feature that is directed to the bur in order to cool down the operating area.

The *Stainless Turbine* handpiece models of the S-Max M and S-Max pico series have a one-touch quick connect coupling system that allows for the attachment of couplings to the handpieces. When the handpiece and coupling are joined together, a locking mechanism functions to prevent the handpiece from being removed from the coupling during use. The connection mechanism of the handpiece and coupling also has a swivel adapter which allows the handpiece to swivel when connected to the coupling and dental unit. The coupling and hose of the dental unit will be connected using a 5-, 4-, 3-, or 2-hole connector that meets ISO 9168 specifications. The *Stainless Turbine* handpieces of the Pana-Max Plus and Pana-Max Plus2 series connect directly to the hose of the dental unit. Direct connection to the dental unit can be made with a 4-hole connection that also meets ISO 9168 specifications.

All *Stainless Turbine* handpieces are equipped with a Clean Head System (CHS), which is intended to reduce the ingress of foreign matter into the handpiece, and all *Stainless Turbine* couplings have an integrated Anti-Retraction Valve (ARV), which is intended to help reduce cross-contamination in the water lines of the handpiece and dental unit.

Tables 1 and 2 provide a comparison of the proposed device to both the predicate and reference devices. The tables illustrate the similarities and difference between the devices.

**Table 1: Comparison of the Proposed Device to the Predicate Devices**

| | **Proposed Device** | **Primary Predicate** | **Secondary Predicate** |
|---|---|---|---|
| | Stainless Turbine | T1 / T2 / T3 Turbine family with serial no. > 600,000 | Ti-Max X450 |
| 510(k) Submitter [Number] | NAKANISHI INC. [K203791] | Sirona Dental Systems GmbH [K131319] | NAKANISHI INC. [K112024] |
| Indications for Use | The Stainless Turbine is intended for the following applications: Caries removal, Cavity and crown preparation, Removal of dental restorations (fillings and prostheses), Finishing of teeth and dental restorations (preparation / adjustment).<br>The Coupling is intended for the following applications: A connection device to transfer energy (air, water, light) required for handpieces. | The turbines of the T1 / T2 / T3 Turbine family are intended for the Preparation of cavities and crowns, Removal of carious material, Removal of fillings, Processing of tooth and restoration surfaces, Reducing hard tooth structure. | The Ti-Max X450 is an air-powered dental handpiece with intended use of being a surgical tool for impacted third molar removal and periodontal procedures for which a conventional handpiece would be used. The Ti-Max X450 is intended for use with a friction grip bur that conforms to ISO 1797-1 standard. Recommended supply air pressure is between 0.22 and 0.30 MPa, which results in high speed bur rotation (approximately 380,000 to 450,000 RPM). |
| Model Numbers | <u>Handpiece Series</u><br>S-Max M:<br>M500, M500L, M500K, M500KL, M500SL, M600, M600L, M600K, M600KL, M600SL, M600WLED, M800, M800L, M800KL, M800WL, M900, M900L, M900K, | <u>T1 Turbines</u><br>T1 Control:<br>T1 Control S, T1 Control K, T1 Control W, T1 Control N<br>T1 Boost:<br>T1 Boost S, T1 Boost K, T1 Boost W, T1 Boost N | X450L, X450KL, X450SL, X450STL, X450WHL, X450MWL, X450M4, X450, X450 5H, X450BLED, X450WLED |

| | Proposed Device | Primary Predicate | Secondary Predicate |
|---|---|---|---|
| | Stainless Turbine | T1 / T2 / T3 Turbine family with serial no. > 600,000 | Ti-Max X450 |
| | M900KL, M900W, M900WL<br>Pana-Max Plus: PAP-MU M4, PAP-SU M4<br>Pana-Max Plus2: PAP2-MU M4, PAP2-SU M4<br>S-Max pico: S-Max pico, S-Max pico KL, S-Max pico SL, S-Max pico BLED, S-Max pico WLED, S-Max pico WHL, S-Max pico MWL, S-Max pico STL<br><u>Coupling Series</u><br>LED: PTL-CL-LED, PTL-CL-LED III, KCL-LED<br>Glass Fiber Rod: PTL-CL-FV-T<br>No Light Irradiation: FM-CL-M4, FM-CL-M4-T, QD-J B2/B3, QD-J M4 | T1 mini: T1 mini S, T1 mini K, T1 mini W, TI mini N<br><u>T2 Turbines</u><br>T2 Control: T2 Control S, T2 Control K, T2 Control W, T2 Control N<br>T2 Boost: T2 Boost S, T2 Boost K, T2 Boost W, T2 Boost N<br>T2 mini: T2 mini S, T2 mini K, T2 mini W, T2 mini N<br><u>T3 Turbines</u><br>T3 Boost: T3 Boost S, T'3 Boost K, T3 Boost W, T3 Boost NQ<br>T3 mini: T3 mini S, T3 mini K, T3 mini W, T3 mini NQ | |
| Power Source | Compressed Air, Lighting powered by Dental Unit | Compressed Air, Lighting powered by Dental Unit | Compressed Air, Lighting powered by Dental Unit |
| Device Features | Clean Head System and Anti-Retraction Valve | Information Not Available | Clean Head System and Anti-Retraction Valve |

| | **Proposed Device** | **Primary Predicate** | **Secondary Predicate** |
|---|---|---|---|
| | Stainless Turbine | T1 / T2 / T3 Turbine family with serial no. > 600,000 | Ti-Max X450 |
| Coupling Dimensions or Type | Direct Connection to 4-hole types. (ISO 9168)<br>Connection via swivel adapter to 5-, 4-, 3-, and 2-hole types. (ISO 9168) *[1] | Connection to 4- and 6-hole types. (ISO 9168) | Direct Connection to 4- and 5-hole types. (ISO 9168)<br>Connection via swivel adapter to 4-, 3-, and 2-hole types. (ISO 9168) |
| Accessories | Handpiece Series<br>Spray Nozzle: Excluding PAP-MU M4, PAP-SU M4, PAP2-MU M4, PAP2-SU M4<br>Cleaning Wire: All handpiece models<br>Head Cap Wrench: All handpiece models<br>Coupling Series<br>KCL Coupling Wrench: KCL-LED<br>PTL Coupling Wrench: PTL-CL-LED, PTL-CL-LED III, PTL-CL-FV-T, FM-CL-M4, FM-CL-M4-T | Sirona connection spray adapter<br>KaVo connection spray adapter<br>W&H connection spray adapter<br>NSK MachLite connection spray adapter<br>NSK QD-J connection spray adapter<br>Morita connection spray adapter<br>Yoshida connection spray adapter<br>Black nozzle adapter<br>Spray water cartridge<br>T1 Spray<br>Chuck tester | Spray Nozzle: Excluding X450M4, X450 5H<br>Cleaning Wire: All handpiece models<br>PTL O-ring Set: Included in the package X450L, X450 |
| Rotation Speed | 325,000 – 450,000 $min^{-1}$ | 250,000 – 400,000 $min^{-1}$ | 380,000 – 450,000 $min^{-1}$ |

| | **Proposed Device** | **Primary Predicate** | **Secondary Predicate** |
|---|---|---|---|
| | Stainless Turbine | T1 / T2 / T3 Turbine family with serial no. > 600,000 | Ti-Max X450 |
| Torque | ≥ 0.05 N·cm | Information Not Available | ≥ 0.09 N·cm |
| Noise-Level | ≤ 80 dBA | Information Not Available | ≤ 80 dBA |
| Supply Air Pressure | 0.18 – 0.30 MPa | Information Not Available | 0.22 – 0.30 MPa |
| Supply Water Pressure | 0.08 – 0.20 MPa | Information Not Available | 0.05 – 0.20 MPa |

*[1] Swivel adapter is the same as coupling.

**Table 2: Comparison of the Proposed Device to the Reference Devices**

| | Proposed Device | Reference Device | Reference Device |
|---|---|---|---|
| | Stainless Turbine | Mach-Sigma Handpiece, Ultrapush | Mach-Sigma Handpiece, Ultrapush, Models Mach-Sigma MU (Minihead), Mach-Sigma SU (Std. Head), Mach-Sigma TU (Torque Head) |
| 510(k) Submitter [Number] | NAKANISHI INC. [K203791] | NAKANISHI INC. [K980162] | NAKANISHI INC. [K991701] |
| Indications for Use | The Stainless Turbine is intended for the following applications: Caries removal, Cavity and crown preparation, Removal of dental restorations (fillings and prostheses), Finishing of teeth and dental restorations (preparation / adjustment).<br><br>The Coupling is intended for the following applications: A connection device to transfer energy (air, water, light) required for handpieces. | The device is intended for use in general dental applications, where high speed cutting is required, such as cutting a tooth for crown preparation, cavity preparation, removing metal crown or fillings.<br><br>This device uses a USA-patented, long proven check valve, a Non-Retraction Valve, in the water line of the handpiece to prevent the oral fluids, which could be contaminated, from being drawn into the handpiece spray port(s) of the handpiece. The contaminants could reach beyond the handpiece, but this check valve, as being installed in the handpiece body, prevents them from reaching beyond the handpiece. | The device is intended for use in general dental applications, where high speed cutting is required, such as cutting a tooth for crown preparation, cavity preparation, removing metal crown or fillings.<br><br>In addition to the above Indications for Use, we would like to emphasize, as a USA-patented, long proven dust shield mechanism, Clean-Head System, is used as an integral part of the turbine cartridge, that this device is able to substantially reduce bacterial contamination of the handpiece exhaust air lines to the dental unit. |

| | Proposed Device | Reference Device | Reference Device |
|---|---|---|---|
| | Stainless Turbine | Mach-Sigma Handpiece, Ultrapush | Mach-Sigma Handpiece, Ultrapush, Models Mach-Sigma MU (Minihead), Mach-Sigma SU (Std. Head), Mach-Sigma TU (Torque Head) |
| Device Models | <u>Handpiece Series</u><br>S-Max M: M500, M500L, M500K, M500KL, M500SL, M600, M600L, M600K, M600KL, M600SL, M600WLED, M800, M800L, M800KL, M800WL, M900, M900L, M900K, M900KL, M900W, M900WL<br>Pana-Max Plus: PAP-MU M4, PAP-SU M4<br>Pana-Max Plus2: PAP2-MU M4, PAP2-SU M4<br>S-Max pico: S-Max pico, S-Max pico KL, S-Max pico SL, S-Max pico BLED, S-Max pico WLED, S-Max pico WHL, S-Max pico MWL, S-Max pico STL<br><u>Coupling Series</u><br>LED: PTL-CL-LED, PTL-CL-LED III, KCL-LED<br>Glass Fiber Rod: PTL-CL-FV-T | Mach-Sigma MU (Mini), Mach-Sigma SU (Standard), Mach-Sigma TU (Torque) | Mach-Sigma MU (Mini Head), Mach-Sigma SU (Standard Head), Mach-Sigma TU (Torque Head |

| | Proposed Device | Reference Device | Reference Device |
|---|---|---|---|
| | Stainless Turbine | Mach-Sigma Handpiece, Ultrapush | Mach-Sigma Handpiece, Ultrapush, Models Mach-Sigma MU (Minihead), Mach-Sigma SU (Std. Head), Mach-Sigma TU (Torque Head) |
| | No Light Irradiation: FM-CL-M4, FM-CL-M4-T, QD-J B2/B3, QD-J M4 | | |
| Power Source | Compressed Air, Lighting powered by Dental Unit | Compressed Air | Compressed Air |
| Coupling Dimensions or Type | Direct Connection to 4-hole types. (ISO 9168)<br>Connection via swivel adapter to 5-, 4-, 3-, and 2-hole types. (ISO 9168) *[1] | Direct Connection to 4-hole types. (ISO 9168) | Direct Connection to 4-hole types. (ISO 9168) |
| Device Features | Clean Head System and Anti-Retraction Valve | Anti-Retraction Valve | Clean Head System and Anti-Retraction Valve |
| Rotation Speed | 325,000 – 450,000 $min^{-1}$ | Standard: 400,000 $min^{-1}$<br>Mini: 400,000 $min^{-1}$<br>Torque: 320,000 $min^{-1}$ | Standard: 400,000 $min^{-1}$<br>Mini: 400,000 $min^{-1}$<br>Torque: 320,000 $min^{-1}$ |
| Torque | ≥ 5.0 g·cm | Standard: 8.0 g·cm<br>Mini: 7.5 g·cm<br>Torque: 13 g·cm | Standard: 8.0 g·cm<br>Mini: 7.5 g·cm<br>Torque: 13 g·cm |
| Noise-Level | ≤ 80 dBA | 75 dBA max. at 2 kg/cm² air | 75 dBA max. at 2 kg/cm² air |
| Supply Air Pressure | 0.18 – 0.30 MPa (1.8 – 3.0 kg/cm²) | 1.8 – 2.0 kg/cm² | 1.8 – 2.0 kg/cm² |
| Supply Water Pressure | 0.08 – 0.20 MPa (0.8 – 2.0 $kg/cm^2$) | ≤ 2.0 kg/cm² | ≤ 2.0 kg/cm² |

*[1] Swivel adapter is the same as coupling.

In summary, the following minor differences exist between the subject device and the predicate and reference devices:

- Intended Use:
  - An additional accessory has been included in the Indications for Use for the subject device
- Technological characteristics:
  - Dimensions and weight
  - Number and functions of compatible accessories
  - Compatible coupling/connection types (all types are ISO 9168 standard compliant)

These differences do not raise different questions of safety and effectiveness.

Summary of Performance Testing:

The *Stainless Turbine* handpieces and couplings were developed and are produced under the consideration of all applicable technical standards, internal specifications, and FDA guidance documents. The devices' conformance with applicable international and internal standards was verified over the course of bench testing. Tests were performed on the handpieces including verification/validation testing to internal functional specifications which demonstrated that the device is substantially equivalent to FDA cleared devices. Sterilization has been validated in conformance to the FDA recognized consensus standard 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*. Documentation was provided demonstrating that the *Stainless Turbine* handpieces and couplings comply with the requirements stated in the FDA guidance document *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff*. Biocompatibility evaluations were selected in accordance with ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Evaluation and testing* and the FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and Testing*. In addition, testing for performance of the handpieces was conducted in accordance with ISO 14457:2012 *Dentistry - Handpieces and motors*.

Conclusion:

NAKANISHI INC. considers the *Stainless Turbine* handpieces to be substantially equivalent to the predicate devices referenced above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.