June 2, 2023

Nakanishi Inc.
Yuki Gomi
RA Dept
700 Shimohinata
Kanuma, Tochigi 322-8666
Japan

Re: K230888
Trade/Device Name: Titanium Turbine
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: March 31, 2023
Received: April 3, 2023

Dear Yuki Gomi:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE.,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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230888

Device Name
Titanium Turbine

Indications for Use *(Describe)*

The Titanium 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).

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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Section 5. 510(k) Summary

K230888

Date Prepared: December 20, 2022

Submitter

NAKANISHI INC.
700 Shimohinata
Kanuma Tochigi 322-8666, Japan
TEL: +81-289-64-7277
FAX: +81-289-62-9738
Contact: Masaaki Kikuchi
m-kikuchi@nsk-nakanishi.co.jp

Device

Device Name:	Titanium Turbine
Common Name:	Handpiece, Air-Powered, Dental
Regulation Number:	21 CFR 872.4200
Regulation Name:	Dental Handpiece and Accessories
Regulatory Class:	I
Product Codes:	EFB

Predicate Device

Predicate Device Name:	Stainless Turbine
510(k) Number:	K203791
Company Name	NAKANISHI INC.
Reference Device Name:	MASTERTORQUE LUX 8900 L
510(k) Number:	K130560
Company Name	KALTENBACH & VOIGT GMBH

Device Description

The Titanium Turbine is an air-driven dental handpiece used by qualified dental professionals. The Titanium Turbine is connected to a dental unit via a coupling and uses supplied compressed air to rotate a dental bar attached to its tip at a high speed (380,000-450,000 min^{-1}) to enable dental treatment.
Titanium Turbine is mainly made of titanium and can be reused by reprocessing.
This device is equipped with a Clean Head System that reduces suck-buck into the head and exhaust line, thereby reducing cross-contamination of the air lines. Titanium Turbine is also equipped with a quick stop system that reduces the time required to stop rotation, thereby improving oral cavity safety, and reducing suck-buck.

Indications for Use

The Titanium 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).

Comparison of Technological Characteristics with the Predicate Device

A comparison of the technical characteristics of the subject device and the previous example is shown below.

Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
Device Name	Titanium Turbine	Stainless Turbine	MASTERTORQUE LUX 8900 L	-
Indications for Use	The Titanium 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 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 MASTERtorque LUX 8900 L is intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.	Identical: The subject device and the reference device differ only in the device name. Similar: The subject device and the reference device have similar indications for use.
Principles of Operation	Air from a dental chair, coolant water, coolant chip air, the power for light will be supplied to the handpieces via couplings.	Air from a dental chair, coolant water, coolant chip air, the power for light will be supplied to the handpieces via couplings.	Through the tube and the MULTIflex coupling connected to a dental unit, the air-powered handpiece receives the air for high speed turbine, the cooling water and air for cutting treatment through pouring holes and light for illumination the iperation area.	Identical: The principles of operation of the subject device and the predicate device are identical. Similar: The principles of operation of the subject device and reference devices are similar.
Power Source	Compressed Air, Lighting	Compressed Air, Lighting	Compressed Air, Lighting	Identical

Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
	powered by Dental Unit	powered by Dental Unit	powered by Dental Unit	
Head Size (Diameter x Height)	φ9.0 x H 10.8 mm	φ8.6 x H 9.1 – φ12.1 x H 13.3 mm	φ12.5 x H 13.0 mm	Difference: There is a difference in the head size of the subject device. The head size of the subject device falls within the head size range of the predicate device, supporting substantial equivalence.
Weight	33 – 39 g	44 – 65 g	Information not available	Difference: There is a difference in the weight of the subject device. ISO 14457 conformance testing is performed to support substantial equivalence.
Head Angle	100°	90°	100°	Difference: There is a difference in the head angle of the subject device. However, it is identical to the head angle of the reference device and supports substantial equivalence.
Rotation Speed	380,000 - 450,000 min^{-1}	325,000 – 450,000 min^{-1}	340,000 – 400,000 min^{-1}	Similar: The rotational speeds of the subject device fall within the range of the predicate device, and the maximum

Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
				rotational speeds are identical.
Torque	≥ 0.05 cN·m	≥ 0.05 cN·m	Information not available	Identical
Noise-Level	≤ 80 dBA	≤ 80 dBA	Information not available	Identical
Chuck Design	Push Button	Push Button	Push Button	Identical
Bur Type	ISO 1797 Type 3 Φ1.59 – 1.60 mm	ISO 1797-1 Type 3 Φ1.59 – 1.60 mm	ISO 1797-1 Type 3 Φ1.59 – 1.60 mm	Identical: The only difference is the version of the standard.
Power	20 W	9 – 26 W	31 W	Similar: The power falls within the range of the precedent device.
Device Features	Clean Head System Quick Stop System	<u>All handpices:</u> Clean Head System <u>S-Max pico BLED, All couplings:</u> Anti-Retraction Valve	Direct Stop Technology	Identical: The Clean Head System has the same functionality as the precedent device. Difference: The Quick Stop System of the subject device is a feature not found in the predicate device. However, it is similar to the Direct Stop Technology of the reference device and supports substantial equivalence.
Coating	DURAGRIP	Sand blasting finish	Plasmatec coating	Difference: The subject device differs from the predicate and reference devices because

Characteristics	Subject Device	Predicate Device	Reference Device	Comparison
				DURAGRIP is used for the coating. Biocompatibility testing confirms compliance with ISO 10993-1 and supports substantial equivalence.
Lubrication	PANA SPRAY Plus (K163483)	PANA SPRAY Plus (K163483)	KaVo QUATTROcare (K071288)	Identical
Sterilization Type	Steam sterilization (Autoclave)	Steam sterilization (Autoclave)	Steam sterilization (Autoclave)	Identical
Direct/Indirect patient Contacting Materials	Stainless Steel, Stainless Steel (CrN coated), Fluororubber, Glass, Titanium (CrN coated), Brass (NiCr plating), Resin	Stainless Steel, Fluororubber, Glass, Brass (Ni plating), Brass (NiCr plating), Resin	Stainless Steel, german silver (nickel – chromium coated), PEEK and Fluoride Rubber Viton	Difference: The subject device differs from the predicate and reference devices because it is made of titanium. Biocompatibility testing confirms compliance with ISO 10993-1 and supports substantial equivalence.

Performance Testing

The following performance testing were performed to support substantial equivalence.

Non-Clinical Performance Testing:

The Titanium Turbine of the subject device was provided with verification/validation testing to support substantial equivalence. These test results demonstrate compliance with the requirements of the following harmonized standards.

- ISO 14457:2017 “Dentistry - Handpieces and motors”
- 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”

Biocompatibility:

The Titanium Turbine of the subject device is classified as surface contact device and devices that have limited contact with mucous membranes (less or equal to 24 hours) based on the intended use. For biocompatibility evaluation, the following tests were performed to meet the requirements of ISO 10993-1:2018 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” and the FDA guidance, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk process"*.

- ISO 10993-5 Cytotoxicity Test
- ISO 10993-10 Sensitization Test
- ISO 10993-10 Irritation Test
- ISO 10993-11 Acute Systemic Toxicity Test
- ISO 10993-11 Pyrogen Test

Clinical Study:

No clinical study was required to support a determination of the substantial equivalence of the Titanium Turbine.

Conclusion

The performance test results support the substantial equivalence of the subject Titanium Turbine to the precedent device. The differences between the subject device and the precedent device do not raise different issues of safety and effectiveness. The same technical characteristics, including indications, also lead to the conclusion that the Titanium Turbine is substantially equivalent to the precedent device.