April 25, 2024

NAKANISHI INC.
% Takahiro Haruyama
President
Globizz Corpration
1411 W. 190th St.
Suite 200
Gardena, California 90248

Re: K233308
Trade/Device Name: Air Motor (Model name: FX204 M4); Air Motor (Model name: M205)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB
Dated: March 7, 2024
Received: March 13, 2024

Dear Takahiro Haruyama:

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.

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

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.

Submission Number *(if known)*

K233308

Device Name

Air Motor (Model name: FX204 M4)
Air Motor (Model name: M205)

Indications for Use *(Describe)*

Air Motor is intended for the following application(s): Driving the handpiece for the tooth restoration, prophylaxis, and root canal preparation.

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)#: K233308 **510(k) Summary** Prepared on 2024-04-25

Contact Details

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Kanuma Tochigi, 322-8666, Japan
Applicant Contact Telephone: +81-289-64-7277
Applicant Contact: Masaaki Kikuchi
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Device Name

Device Trade Name: Air Motor (Model name: FX204 M4)
Air Motor (Model name: M205)
Common Name: Dental handpiece and accessories
Classification Name: Handpiece, Air-Powered, Dental
Regulation Number: 872.4200

Device Class: I
Product Codes: EFB

Legally Marketed Predicate Devices

Predicate Device #: K143704
Predicate Trade Name: Advanced Air System
Product Code: EFB

Reference Device #: K162926
Predicate Trade Name: W&H Air-Powered Handpieces And Handpiece Attachments
Product Code: EFB

Device Description Summary

The air motor converts the compressed air supplied from the dental unit into rotary motion. The rotation is transmitted to instruments for tooth restoration, prophylaxis, and root canal preparation connected to straight and geared angle handpieces.

Intended Use/ Indications for Use

Air Motor is intended for the following application(s): Driving the handpiece for the tooth restoration, prophylaxis, and root canal preparation.

DEVICE AND PREDICATE COMPARISON TABLE-1

For Air Motor, FX204 M4 (model without spray)

Descriptive Information	Subject Device	Primary Predicate Device	Reference Device	Judgement
Device Name	**Air Motor, FX204 M4**	Advanced Air System (RM-25 L RM)	Air-Powered Handpieces and Handpiece Attachments **(AM-25 RM: model w/o spray)**	
K number	K233308	K143704	K162926	
Indication for Use	Air Motor is intended for the following application(s): Driving the handpiece for the tooth restoration, prophylaxis, and root canal preparation.	Pneumatic drive system for dental handpieces and dental air motors, which is intended to be used in general dental applications such as: removal of decayed materials, cavities and crown preparations, removal of filings, finishing of tooth and restoration surfaces, polishing, prophylaxis and endodontics	The turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces. The dental handpiece/contra-angle is intended for the following applications: Removal of decayed materials, cavities and crown cement, removal of fillings, finishing and polishing of tooth and restoration surfaces.	**Same:** all devices are intended for general dental applications including restoration, dental cleaning (prophylaxis), and root canal preparation
Device Description	The air motor converts the compressed air supplied from the dental	The Advanced Air System is intended for dental transmission instruments	The Air-powered Handpieces contain pipes inside which supply air for	**Same**: all devices use air motors, are pneumatically driven,

	unit into rotary motion. The rotation is transmitted to instruments for tooth restoration, prophylaxis, and root canal preparation connected to straight and geared angle handpieces.	used in the field of preventive dentistry, restorative dentistry such as cavity preparation and prosthodontics such as crown preparation and endodontics. The system consists of the control unit (AC-1.0), which is designed to be built in a dental chair. As an attachment the air-driven handpiece (RK-97 L, RG- 97 L, and/or RK-94 L) or the air motor (RM-25 L RM) can be used. The air-driven handpiece is equipped with a speed sensor, which is connected to a control module that regulates the applied air pressure to the handpiece through a proportional valve in order to maintain constant speed throughout the dental treatment	driving the turbine's impeller as well as supply air and water for creating spray exhausting through 3, 4 or 5 ports located in the handpiece's head and intended for cooling the working area as well as the rotating bur. Depending on the type of handpiece – the handle might contain an integrated circuit board and wire bundles, for supplying current and voltage to a head sided assembled LED light source. The Handpiece Attachments also contain pipes inside which supply air and water for spray exhausting and for cooling the working area as well as the rotating bur. Depending on the type of handpiece – the handle might contain an integrated circuit board and wire bundles, for supplying current and voltage to a head-sided assembled LED light source.	and used for driving dental handpieces.
Supply air	0.20 – 0.25 MPa	0.52 – 0.59 MPa	unknown	<u>Different</u> The subject device has

				lower pressure
Optic lighting	no	yes	no	**Same** with Air-Powered Handpieces and Handpiece Attachments
Speed range	19,800 - 24,200 min^{-1} (0.25MPa)	2,000 – 20,000 rpm	25,000 +/–10%	*Similar* All devices have similar upper speed range
Max. air consumption	< 66NL/min	1.5 l/s (3.2 cfm)	42-50NI/min	*Similar* with Air-Powered Handpieces and Handpiece Attachments.
Weight	61.7g	39 g	73g	*Similar* weight to Air-Powered Handpieces and Handpiece Attachments
Performance Testing	Performance: ISO 14457:2017 Sterilization: AAMI/ANSI/ISO 17665-1:2006 Cleaning: Guidance for the Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff.	Electrical Safety Tests: IEC 60601-1:2005 Electromagnetic Compatibility: IEC 60601-1-1:2007 Product testing of handpiece function and life cycle testing: ISO 14457:2012 Software validation: IEC 62304:2006 Usability validation: IEC 62366:2007 Thermal safety: IEC 62471:2006	Product testing of the handpieces function and life cycle testing: ISO 14457:2012 EMC Testing: IEC 60601-1-2:200 Thermal safety: IEC 62471:2006	*Similar* All the devices passed the ISO 14457 Performance testing. Relevant testing to predicate devices. ・ISO 14457 2017 Conformity confirmation report ・Drop test report ・Reprocessing resistance test report ・Water leakage and water ingress test report ・Statistical calculation of sample size

				・Equivalence confirmation for package test report ・Vibration test report ・Sterilization validation report ・Conformity assessment to the product family group for sterilization ・Product family group conformity confirmation on cleaning validation ・Cleaning validation report ・Cleaning validation of accessories
Biocompatibility	ISO 7405: 2018 AAMI/ANSI/ISO 10993-1: 2018	ISO 7405:2008 ISO 10993-5:2009	ISO 7405:2008 ISO 10993-5:2009 Evaluation of biocompatibility is based upon the fact that patient contacting materials in the subject handpiece are identical to those in the previously cleared predicates (K143704 and K070663), which as handpieces and handpiece attachments, present the same level and duration of contact. In	*Similar* Biocompatibility testing confirms compliance with ISO 10993-1 and supports substantial equivalence. Relevant testing to predicate devices. ・Biological safety evaluation report ・Confirmation of effectiveness and biological safety of accessory

			addition, Cytotoxicity Testing per EN ISO 10993-5:2009 was performed. This evaluation meets the requirements of ISO 7405:2008 for preclinical evaluation of biocompatibility of dental devices.	・MSDS
Clinical Testing	NO	NO	NO	**Same**
Air/water port	No spray	No spray	No Spray	**Same**
Dimensions	78.3 x ϕ20 mm	87,87 x ϕ20 mm	Unknown	*Similar* dimensions with Advanced Air System. ISO 14457 performance testing supports substantial equivalence.
Patient-contacting portions	Direct contact: No Indirect contact: No	Direct contact: Unknown Indirect contact: No	Direct contact: Unknown Indirect contact: No	*Similar* Conformity to ISO 10993-1 supports substantial equivalence.
Handpiece Connection	ISO 3964	Unknown	ISO 3964	**Same** with Air-Powered Handpieces and Handpiece Attachments.
Hose Connection	ISO 9168	Unknown	ISO 9168	**Same** with Air-Powered Handpieces and Handpiece Attachments.
Lubricant	PANA SPRAY Plus (K163483)	Unknown	W&H Service Oil F1, MD-400 W&H Assistina	*Similar* with Air-Powered Handpieces and Handpiece Attachments. Conformity to ISO 10993-1 supports substantial equivalence.

Discussion:

Intended use: same. The intended use for the subject device Air Motor FX204 M4 and its predicate device Advanced Air System RM-25 L RM is for general dental applications.
The principle of the operating technology: same (pneumatically driven).

There are differences in the two devices features, such as “supply air pressure”. To verify if the supply air pressure of the subject device affects its efficiency, we compared the subject device and the reference device under air supply pressures, reflecting the range for the subject device and reference device. The performance gap at the lower air supply pressure limit was relatively small. Despite this, the product's performance as an air motor remains sufficient for power transmission to attachments and cutting and grinding teeth (Test Report_Equivalence Check of Similar Devices). In terms of performance, it is equivalent to the reference device.

Therefore, we conclude that the subject device Air Motor FX204 M4 and its predicate devices Advanced Air System RM-25 L RM and Air-Powered Handpieces and Handpiece Attachments AM-25 RM are substantially equivalent.

DEVICE AND PREDICATE COMPARISON TABLE-2

For Air Motor, M205 (Internal Spray equipped)

Descriptive Information	Subject Device	Primary Predicate Device	Reference Device	Judgement
Device Name	**Air Motor, M205**	Advanced Air System (RM-25 L RM)	Air-Powered Handpieces and Handpiece Attachments **(AM-25 A RM, model with spray)**	
K number	K233308	K143704	K162926	
Indication for Use	Air Motor is intended for the following application(s): Driving the handpiece for the tooth restoration, prophylaxis, and root canal preparation.	Pneumatic drive system for dental handpieces and dental air motors, which is intended to be used in general dental applications such as: removal of decayed materials, cavities and crown preparations, removal of filings, finishing of tooth and restoration surfaces, polishing, prophylaxis and endodontics	The turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces. The dental handpiece/contra-angle is intended for the following applications: Removal of decayed materials, cavities and crown cement, removal of fillings, finishing and polishing of tooth and restoration surfaces.	*Similar*: all devices are intended for general dental applications including restoration, dental cleaning (prophylaxis), and root canal preparation
Device Description	The air motor converts the compressed air supplied from the dental unit into rotary motion. The rotation is	The Advanced Air System is intended for dental transmission instruments used in the field of preventive dentistry,	The Air-powered Handpieces contain pipes inside which supply air for driving the turbine's impeller as well as supply	**Same**: all devices use air motors, are pneumatically driven, and used for driving dental handpieces.

	transmitted to instruments for tooth restoration, prophylaxis, and root canal preparation connected to straight and geared angle handpieces. M205 has a water injection mechanism.	restorative dentistry such as cavity preparation and prosthodontics such as crown preparation and endodontics. The system consists of the control unit (AC-1.0), which is designed to be built in a dental chair. As an attachment the air-driven handpiece (RK-97 L, RG- 97 L, and/or RK-94 L) or the air motor (RM-25 L RM) can be used. The air-driven handpiece is equipped with a speed sensor, which is connected to a control module that regulates the applied air pressure to the handpiece through a proportional valve in order to maintain constant speed throughout the dental treatment	air and water for creating spray exhausting through 3, 4 or 5 ports located in the handpiece's head and intended for cooling the working area as well as the rotating bur. Depending on the type of handpiece – the handle might contain an integrated circuit board and wire bundles, for supplying current and voltage to a head sided assembled LED light source. The Handpiece Attachments also contain pipes inside which supply air and water for spray exhausting and for cooling the working area as well as the rotating bur. Depending on the type of handpiece – the handle might contain an integrated circuit board and wire bundles, for supplying current and voltage to a head-sided assembled LED light source.	The subject device, "Air Motor M205" has the same technology as "Air-Powered Handpieces and Handpiece Attachments, model AM-25 A RM" as both are equipped with pipes inside that supply air and water.
Supply air	0.20 – 0.25 MPa	0.52 – 0.59 MPa (75 – 85 psi)	unknown	<u>Different</u> The subject device has lower pressure
Optic lighting	no	yes	no	**Same** with Air-Powered

				Handpieces and Handpiece Attachments
Speed range	19,800 - 24,200 min^{-1} (0.25MPa)	2,000 – 20,000 rpm	25,000 +/–10%	*Similar* All devices have similar upper speed range
Max. air consumption	< 66 NL/min	1.5 l/s (3.2 cfm)	42-50NI/min	*Similar* with Air-Powered Handpieces and Handpiece Attachments
Weight	78.2g	39 g (1 34 oz)	73g	*Similar* weight to Air-Powered Handpieces and Handpiece Attachments
Spray water flow acc.to ISO 14457	> 50(ml/min)	Not relevant	> 50(ml/min)	**Same**
Water pressure	1 – 2.5 (bar)	Not relevant	1.5-2.5 (bar)	*Similar range*
Chip air pressure	1.5 – 2.5 (bar)	Not relevant	2-3 (bar)	*Similar range*
Performance Testing	Performance: ISO 14457:2017 Sterilization: AAMI/ANSI/ISO 17665-1:2006 Cleaning: Guidance for the Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff.	Electrical Safety Tests: IEC 60601-1:2005 Electromagnetic Compatibility: IEC 60601-1-1:2007 Product testing of handpiece function and life cycle testing: ISO 14457:2012 Software validation: IEC 62304:2006 Usability validation: IEC 62366:2007 Thermal safety: IEC 62471:2006	Product testing of the handpieces function and life cycle testing: ISO 14457:2012 EMC Testing: IEC 60601-1-2:200 Thermal safety: IEC 62471:2006	*Similar* All the devices passed the ISO 14457 Performance testing Relevant testing to predicate devices. ・ISO 14457 2017 Conformity confirmation report ・Drop test report ・Reprocessing resistance test report ・Water leakage and water ingress test report

				・Statistical calculation of sample size ・Equivalence confirmation for package test report ・Vibration test report ・Check valve effect verification test report ・Sterilization validation report ・Conformity assessment to the product family group for sterilization ・Product family group conformity confirmation on cleaning validation ・Cleaning validation report ・Cleaning validation of accessories
Biocompatibility	ISO 7405: 2018 AAMI/ANSI/ISO 10993-1: 2018	ISO 7405:2008 ISO 10993-5:2009	ISO 7405:2008 ISO 10993-5:2009 Evaluation of biocompatibility is based upon the fact that patient contacting materials in the subject handpiece are identical to those in the previously cleared predicates (K143704 and K070663),	*Similar* Biocompatibility testing confirms compliance with ISO 10993-1 and supports substantial equivalence. Relevant testing to predicate devices. ・Biological safety evaluation report

			which as handpieces and handpiece attachments, present the same level and duration of contact. In addition, Cytotoxicity Testing per EN ISO 10993-5:2009 was performed. This evaluation meets the requirements of ISO 7405:2008 for preclinical evaluation of biocompatibility of dental devices.	・Confirmation of effectiveness and biological safety of accessory ・MSDS
Clinical Testing	NO	NO	NO	**Same**
Air/water port	Spray	No spray	Spray	**Same** with Air-Powered Handpieces and Handpiece Attachments
Dimensions	78.3 x ϕ20 mm	87,87 x ϕ20 mm	Unknown	*Similar* dimensions with Advanced Air System. ISO 14457 conformance testing is performed to support substantial equivalence.
Patient-contacting portions	Direct contact: No Indirect contact: Waterlines	Direct contact: Unknown Indirect contact: No	Direct contact: Unknown Indirect contact: Waterlines	*Similar* with Air-Powered Handpieces and Handpiece Attachments. Conformity to ISO 10993-1 supports substantial equivalence.
Composition of the waterlines	Fluor rubber, Stainless steel, Aluminum based alloy	Not relevant	Unknown	Different Conformity to ISO 10993-1 supports substantial equivalence.
Handpiece Connection	ISO 3964	Unknown	ISO 3964	**Same** with Air-Powered

				Handpieces and Handpiece Attachments.
Hose Connection	ISO 9168	Unknown	ISO 9168	**Same** with Air-Powered Handpieces and Handpiece Attachments.
Lubricant	PANA SPRAY Plus (K163483)	Unknown	W&H Service Oil F1, MD-400 W&H Assistina	*Similar* with Air-Powered Handpieces and Handpiece Attachments. Conformity to ISO 10993-1 supports substantial equivalence.

Discussion:

Intended use: same. The intended use for the subject device Air Motor M205 and its predicate device Advanced Air System RM-25 L RM is for general dental applications.
The principle of the operating technology: same (pneumatically driven).

There are differences in the two devices features, such as “supply air pressure”. To verify if the supply air pressure of the subject device affects its efficiency, we compared the subject device and the reference device under air supply pressures, reflecting the range for the subject device and reference device. The performance gap at the lower air supply pressure limit was relatively small. Despite this, the product's performance as an air motor remains sufficient for power transmission to attachments and cutting and grinding teeth (Test Report_Equivalence Check of Similar Devices). In terms of performance, it is equivalent to the reference device.

Therefore, we conclude that the subject device Air Motor M205 and its predicate devices Advanced Air System RM-25 L RM and Air-Powered Handpieces and Handpiece Attachments AM-25 A RM are substantially equivalent.