November 17, 2022

Nakanishi Inc.
% Yulia Nikova
Regulatory Affairs Manager
Ken Block Consulting LLC
800 E Campbell Road, Suite 202
Richardson, Texas 75081

Re: K222518
Trade/Device Name: FX Contra
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: August 19, 2022
Received: August 19, 2022

Dear Yulia Nikova:

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,

Michael E. Adjodha -S

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)*
K222518

Device Name
FX Contra

Indications for Use *(Describe)*

FX15 / FX15m / FX25 / FX25m
FX Contra is intended for the following application(s):
Caries removal, cavity and crown preparation, removal of dental restorations (fillings and prostheses), finishing and polishing of teeth and dental restorations.

FX57 / FX57m
FX Contra is intended for the following application(s):
Prophylaxis treatment of the surface of teeth and dental restorations.

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 **K222518**

Submitter:	NAKANISHI INC. 700 Shimohinata Kanuma Tochigi 322-8666 Japan	
Contact Person:	NAKANISHI INC. Mr. Masaaki Kikuchi General Manager, Quality/Regulatory Affairs Dept. 700 Shimohinata Kanuma Tochigi 322-8666 Japan TEL: +81-289-64-7277 FAX: +81-289-62-9738 m-kikuchi@nsk-nakanishi.co.jp	
Date Prepared:	November 16, 2022	
Submission Type:	Traditional 510(k)	
Subject Device:	Manufacturer:	NAKANISHI INC.
	Trade/Device Name:	FX Contra
	Common Name:	Handpiece, contra- and right-angle attachment, dental
	Regulation Number:	21 CFR 872.4200
	Regulation Name:	Dental Handpiece and Accessories
	Regulatory Class:	Class I
	Product Code:	EGS
Predicate Device:	Clearance:	K132356 dated January 31, 2014
	Manufacturer:	SciCan GmbH
	Trade/Device Name:	SANAO Dental Handpieces
	Common Name:	Handpiece, contra- and right-angle attachment, dental
	Regulation Number:	21 CFR 872.4200
	Regulation Name:	Dental Handpiece and Accessories
	Regulatory Class:	Class I
	Product Code:	EGS

Device Description:

The FX Contra includes six models: FX15, FX15m, FX25, FX25m, FX57, and FX57m. The FX Contra handpieces are reusable contra-angle handpieces, driven by an ISO 3964 compliant electronic micromotor or air motor, that are intended for use in a healthcare facility/hospital setting by a trained health care professional in the field of general dentistry. The FX Contra handpieces are designed for general applications to prepare dental cavities for restorations (FX15/FX15m/FX25/FX25m) and for prophylactic teeth cleaning (FX57/FX57m).

The FX Contra handpieces feature ISO 3964 compliant handpiece coupling connecting them to a dental unit through either a micromotor or an air motor. By these means the handpieces receive the energy for the gear for dental treatment. The maximum drive speed is 40,000 min^{-1} for FX15, FX15m, FX25, and FX25m; and 20,000 min^{-1} for FX57 and FX57m. The maximum rotation speed is 10,000 min^{-1} for FX15 and FX15m; 40,000 min^{-1} for FX25 and FX25m; and 5,000 min^{-1} for FX57 and FX57m.

The FX Contra handpieces are composed mainly of stainless steel and aluminum and can be sterilized in a steam sterilizer (autoclave).

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The FX Contra handpieces are intended to be used with ISO 1797-1 compliant burs (FX15, FX15m, FX25 and FX25m) or ISO 13295compliant cups or brush (FX57 and FX 57m).

Principle of Operation / Mechanism of Action:

The principle of operation of the FX Contra handpieces is based on rotatory movement. The contra-angle FX Contra handpieces are driven by energy of electronic micromotor or an air motor, which is converted into mechanical energy through the motor. This mechanical energy is transferred to the drivetrains in the contra-angle handpiece in the form of a rotary movement via an ISO 3964 compliant coupling. The force is transmitted through shafts and gear components to another coupling interface located in the head housing, which is designed for safe insertion and removal of ISO 1797 or ISO 13295 compliant tools. The mechanical energy is passed on to the cutting or polishing part of these tools and thus to the procedure site.

Statement of Intended Use:

FX15 / FX15m / FX25 / FX25m
FX Contra is intended for the following application(s):
Caries removal, cavity and crown preparation, removal of dental restorations (fillings and prostheses), finishing and polishing of teeth and dental restorations.

FX57 / FX57m
FX Contra is intended for the following application(s):
Prophylaxis treatment of the surface of teeth and dental restorations.

Summary of Technological Characteristics:

The intended use, technological characteristics, and functionality are substantially equivalent between the subject FX Contra handpieces and the predicate device. The performance characteristics are also equivalent to the predicate device. Both devices are intended to be used by dental health care professionals (e.g., dentists, periodontists). Both devices are intended for multiple patients use and sterilized by autoclave sterilization. Additionally, the FX Contra handpieces and the predicate device have the same technological characteristics:

- Power source
- Principle of operation
- Push-button auto-chuck

As presented in the brief comparison table below, several differences with respect to technological characteristics were identified between the subject device and the predicate, including but not limited to the transmission gear ratios, compatible burs, and material composition. Performance testing was conducted to support substantial equivalence and demonstrate that these differences do not raise different questions of safety and effectiveness.

A brief summary of the technological characteristics in comparison to those of the predicate device is as follows:

	Subject Device:	**Predicate Device:**
Trade/Device Name	FX Contra	SANAO Dental Handpieces
510(k) Submitter [Number]	NAKANISHI INC. K222518	SciCan GmbH K132356
Device Class	Class I	Class I
Product Code	EGS	EGS

510(k) Summary **K222518**

Regulation	21 CFR 872.4200	21 CFR 872.4200
Indications for Use	FX15 / FX15m / FX25 / FX25m FX Contra is intended for the following application(s): Caries removal, cavity and crown preparation, removal of dental restorations (fillings and prostheses), finishing and polishing of teeth and dental restorations. FX57 / FX57m FX Contra is intended for the following application(s): Prophylaxis treatment of the surface of teeth and dental restorations.	This medical device is only intended for dental treatment in the area of dentistry. It is intended to be used for the following applications: - SANAO 200 L / 40 ST: The removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces. - SANAO 40 / 40 L / 10 / 10 L Cavity preparations, caries excavation, endodontics, surface finishing of tooth and restoration surfaces. - SANAO PSI / PSO: prophylaxis treatment.
Application	General dentistry and prophylaxis	General dentistry and prophylaxis
Model Numbers	General Application FX15 / FX15m / FX25 / FX25m Prophylaxis FX57 / FX57m	General Application SANAO 10 / SANAO 10 L / SANAO 40 / SANAO 40 L / SANAO 200L / SANAO 40 ST Prophylaxis SANAO PSI / SANAO PSO
Power Source	Electronic Micromotor or Air Motor	Electronic Micromotor or Air Motor
Handpiece Chuck Mechanism	Push Button FX15 / FX15m / FX25 / FX25m Not Applicable FX57 / FX57m	Push Button SANAO 10 / SANAO 10 L / SANAO 40 / SANAO 40 L / SANAO 200 L Not Applicable SANAO PSI / SANAO PSO Mechanical SANAO 40 ST
Burs / Cup or Brush	ISO 1797 Type 1 (2.334 - 2.35mm)	ISO 1797 Type 1 (2.35mm)

	FX15 / FX15m / FX25 / FX25m ISO 13295 Type 5 FX57 / FX57m	SANAO 10 / SANAO 10 L / SANAO 40 / SANAO 40 L ISO 1797 Type 2 (2.35mm) SANAO 40 ST ISO 1797 Type 3 (1.60mm) SANAO 200 L ISO 13295 Type 3 SANAO PSI ISO 13295 Type 5 SANAO PSO
Transmission Ratio	1:1 FX25 / FX25m 4:1 FX15 / FX15m / FX57 / FX57m	1:1 SANAO 40 / SANAO 40 L / SANAO 40 ST 5:1 SANAO 10 / SANAO 10 L / SANAO PSI / SANAO PSO 1:5 SANAO 200 L
Materials	Stainless Steel Aluminum	Stainless Steel PEEK

Summary of Non-Clinical Performance Testing:

The FX Contra handpieces are developed and produced under considerations of all applicable technical standards, internal specifications, and FDA guidance documents. The product's conformance with applicable international and internal standards was verified in the course of bench testing.

Tests were performed on the subject device including verification/validation testing to internal functional specifications which demonstrated that the device is substantially equivalent. Specifically,

- Sterilization has been validated in conformance to the FDA recognized consensus standard AAMI/ANSI/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."
- Performance has been demonstrated in conformance to ISO 14457:2017 "Dentistry – Handpieces and Motors."
- Cleaning validation was provided demonstrating that the FX Contra handpieces complies with the FDA requirements stated in *Guidance for the Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling - Guidance for Industry and Food and Drug Administration Staff.*

Biocompatibility Testing:

Biocompatibility evaluations were selected in accordance with AAMI/ANSI/ISO 10993-1: 2018 "Biological evaluation of medical devices – Part 1: Evaluation and

testing" and FDA Guidance *Use on International Standard ISO 10993, "Biological evaluation of medical devices – Part 1: Evaluation and Testing"* and included:

- Cytotoxicity per ISO10993-5
- Sensitization per ISO10993-10
- Irritation per ISO10993-10
- Acute Systemic Toxicity per ISO 10993-11
- Pyrogenicity per ISO 10993-11

Clinical Testing: Clinical testing was not required as non-clinical testing is believed to be sufficient for a determination of substantial equivalence of the FX Contra handpieces.

Conclusion: NAKANISHI INC. considers the FX Contra handpieces to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.