May 24, 2023

Nakanishi Inc.
% Dr. Akiko Dohi
Regulatory Scientist
Ken Block Consulting LLC
800 E Campbell Road, Suite 202
Richardson, Texas 75081

Re: K230106
Trade/Device Name: General Cutting Straight
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: January 13, 2023
Received: January 13, 2023

Dear Dr. Akiko Dohi:

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 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)*
K230106

Device Name
General Cutting Straight

Indications for Use *(Describe)*

X65L / X65 / M65

General Cutting Straight 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.

FX65 / FX65m / EX-5B

General Cutting Straight 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. Using a prophy angle, 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

K230106

Applicant/ Sponsor:	NAKANISHI INC. 700 Shimohinata Kanuma, Tochigi, 322-8666 Japan	
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Date Prepared:	January 13, 2022	
Submission Type:	Traditional 510(k)	
New Device:	Manufacturer: Trade Name: Common Name: Classification Name: Product Code: Regulation: Regulatory Class:	NAKANISHI INC. General Cutting Straight Dental straight handpiece Handpiece, Contra- And Right-Angle Attachment, Dental EGS §872.4200, Dental Handpiece and Accessories I
Predicate Device:	Clearance: Manufacturer: Trade Name: Classification Name: Product Code: Regulation: Regulatory Class:	K132356 dated January 31, 2014 SciCan GmbH SANAO Dental Handpieces Handpiece, Contra- And Right-Angle Attachment, Dental EGS §872.4200, Dental Handpiece and Accessories I
Device Description:	The General Cutting Straight is a prescription-only dental straight handpiece used by qualified dental healthcare professionals in general dentistry. The General Cutting Straight includes six models: X65L, X65, M65, FX65m, FX65, and EX-5B. The General Cutting Straight conforms to ISO 14457 and is driven by an ISO 3964-compliant electric or air motor. The General Cutting Straight achieves its intended use in conjunction with an ISO 1797-compliant rotary instrument or a prophy angle that conforms to either ANSI ADA Standard No. 85-2004 (R2009) or ISO 14457. The General Cutting Straight is composed mainly of stainless steel, titanium, or aluminum, depending on the model, and is reusable, requiring cleaning and steam sterilization. The accessories of the General Cutting Straight include the Bur Stopper, Bur Stopper Puller, and E-Type Spay Nozzle. The General Cutting Straight is lubricated with the PANA SPRAY Plus [K163486] using the E-Type Spray Nozzle.	
Principle of Operation / Mechanism of Action:	The General Cutting Straight is driven by an ISO 3964-compliant electric or air motor and transmits the rotational force through the internal spindle to the mounted rotary instruments for achieving its intended use. The models whose transmission ratio is 1:1 transmit the rotational speed as is from the motor to the mounted instrument. The model whose ratio is 4:1 includes a speed reducing gear mechanism and slows down the rotational speed to ¼ prior to transmitting the rotation to the mounted instrument.	

510(k) Summary

Statement of Intended Use:

X65L/X65/M65
General Cutting Straight 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.

FX65/FX65m/EX-5B
General Cutting Straight 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. Using a prophy angle, prophylaxis treatment of the surface of teeth and dental restorations.

Summary of Technological Characteristics:

Technological characteristics of the General Cutting Straight are briefly summarized and compared to those of the predicate device in the table below.

	New Device	Predicate Device
Trade/Device Name	**General Cutting Straight**	**SANAO Dental Handpieces**
510(k) Submitter [K Number]	NAKANISHI INC. [TBD]	SciCan GmbH [K132356]
Product Code	EGS	EGS
Classification Name	Handpiece, Contra- And Right-Angle Attachment, Dental	Handpiece, Contra- And Right-Angle Attachment, Dental
Regulation	21 CFR 872.4200 Dental Handpiece and Accessories	21 CFR 872.4200 Dental Handpiece and Accessories
Device Class	I	I
Indications for Use	<u>X65L/X65/M65</u> General Cutting Straight 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. <u>FX65/FX65m/EX-5B</u> General Cutting Straight 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. Using a prophy angle, 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 200L/40ST: The removal of decayed matter, cavity and crown preparations, the removal of fillings and surface finishing of tooth and restoration surfaces. • SANAO 40/40L/10/10L: Cavity preparations, caries excavation, endodontics, surface finishing of tooth and restoration surfaces. • SANAO PSI/PSO: prophylaxis treatment.
Rx/OTC Use	Rx Only	Rx Only
Application	General dentistry and prophylaxis	General dentistry and prophylaxis

510(k) Summary

	New Device	Predicate Device
Trade/Device Name	**General Cutting Straight**	**SANAO Dental Handpieces**
Models	General dentistry: X65, X65, M65 General dentistry & Prophylaxis: FX65m, FX65, EX-5B	General dentistry: SANAO 200L, 40ST SANAO 40, 40L, 10, 10L Prophylaxis: SANAO PSI, PSO
Materials	Biocompatible per ISO 10993-1	Biocompatible per ISO 10993-1
Driven by	Electric or air motor	Electric or air motor
Coupling with Motor	ISO 3964	ISO 3964
Maximum Input Speed	40,000 min^{-1}	40,000 min^{-1}
Transmission Ratio	1:1 X65L, X65, M65, FX65m, FX65 4:1 EX-5B	1:1 SANAO 40, 40L, 40ST 5:1 SANAO 10, 10L, PSI, PSO 1:5 SANAO 200L
Maximum Output Speed	10,000 min^{-1}: EX-5B 40,000 min^{-1}: X65L, X65, M65, FX65m, FX65	8,000 min^{-1}: SANAO 10 10L, PSI, PSO 40,000 min^{-1}: SANAO 40, 40L, 40ST 200,000 min^{-1}: SANAO 200L
Type of Chuck	Mechanical Chuck (Bur Lock Ring): All models	Push Button: SANAO 200L, 40, 40L, 10, 10L Mechanical Chuck (Clamping ring): SANAO 40ST Not Applicable: SANAO PSI, PSO
Burs	ISO 1797 Type 1 X65L, X65, M65 (Ø2.334-2.35 mm) ISO 1797 Type 2 X65L, X65, M65, FX65m, FX65, EX-5B (Ø2.334-2.35 mm)	ISO 1797 Type 1 SANAO 40, 40L (Ø2.35 mm) SANAO 10, 10L (Ø 2.35 mm) ISO 1797 Type 2 SANAO 40ST (Ø 2.35 mm) ISO 1797 Type 3 SANAO 200L (Ø 1.60 mm)
Prophy Angles	FX65m, FX65, EX-5B with prophy angles conforming to ANSI ADA Standard No. 85-2004 (R2009) or ISO 14457	PSI with Screw-In-Function (with ISO 13295 Type 3) PSO with mandrels with Snap-on-Function (ISO 13295 Type 5)

Summary of Non-Clinical/ Performance Testing:

The General Cutting Straight was developed under applicable international standards, specifications, and FDA guidance documents. NAKANISHI INC. validated reprocessing instructions of the subject device based on 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" and the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." Based on the validation results, NAKANISHI INC. determined that the subject device can be used safely and included the validated reprocessing instructions in the operation manual of the subject device. The operation manual of the subject device is included in Section 13 Proposed Labeling.

NAKANISHI INC. evaluated the biocompatibility of the subject device based on ISO 10993-1:2018 "Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process" and the FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"" and included:

- Cytotoxicity per ISO10993-5
- Sensitization per ISO10993-10
- Intracutaneous Reactivity per ISO10993-10
- Acute Systemic Toxicity per ISO 10993-11
- Material-Mediated Pyrogenicity per ISO 10993-11

Based on the evaluation, NAKANISHI INC. concluded that the subject device is biocompatible.

NAKANISHI INC. conducted performance testing in accordance with ISO 14457:2017 "Dentistry - Handpieces and motors" for the safety and effectiveness of the subject device. All acceptance criteria for the applicable tests were met.

Together, these verification/validation activities successfully demonstrate that the General Cutting Straight performs as intended and raises no new questions regarding either safety or effectiveness when compared to the predicate device.

Clinical Testing:	Clinical testing was not required as the differences from the predicate device are minor and non-clinical testing is believed to be sufficient for a determination of substantial equivalence of the General Cutting Straight.
Conclusion:	Based on the similarities in intended use, principles of operation, and functional design, demonstrating that the General Cutting Straight is as safe, as effective, and performs as well as the predicate device, NAKANISHI INC. considers the General Cutting Straight to be substantially equivalent to the predicate device identified above.