October 27, 2020

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

Re: K202960
Trade/Device Name: General Cutting Contra Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: September 29, 2020
Received: September 30, 2020

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)*

K202960

Device Name
General Cutting Contra Handpiece

Indications for Use *(Describe)*
The General Cutting Contra Handpiece is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY K202960

Submitter:	NAKANISHI INC. 700 Shimohinata Kanuma, Tochigi 322-8666 Japan	
Contact Person:	Mr. Masaaki Kikuchi General Manager/Quality & Regulatory Affairs Dept. TEL: +81-289-64-7277 FAX: +81-289-62-9738 email: m-kikuchi@nsk-nakanishi.co.jp	
Date Prepared:	September 29, 2020	
Submission Type:	Special 510(k)	
Subject Device:	Manufacturer:	NAKANISHI INC.
	Trade Name:	General Cutting Contra Handpiece
	Common Name:	Handpiece, Contra- And Right-Angle Attachment, Dental
	Regulatory Class:	Class I
	Product Code:	EGS
	Regulation:	21 CFR 872.4200, Dental handpiece and accessories
Predicate Device:	Clearance:	K182999 dated April 16, 2019
	Manufacturer:	NAKANISHI INC.
	Trade Name:	General Cutting Contra Handpiece
	Common Name:	Handpiece, Contra- And Right-Angle Attachment, Dental
	Regulatory Class:	Class I
	Classification Name:	Handpiece, Contra- And Right-Angle Attachment, Dental
	Product Code:	EGS
	Regulation:	21 CFR 872.4200, Dental handpiece and accessories
Reference device:	Clearance:	K121901 dated February 28, 2013
	Manufacturer:	NAKANISHI INC.
	Trade Name:	Ti-Max Z45
	Regulatory Class:	Class I
	Classification Name:	Handpiece, Contra- And Right-Angle Attachment, Dental
	Product Code:	EGS
	Regulation:	21 CFR 872.4200, Dental handpiece and accessories
Reference device:	Clearance:	K173905 dated June 19, 2018
	Manufacturer:	NAKANISHI INC.
	Trade Name:	Surgic Pro, Surgic Pro+
	Regulatory Class:	Class I
	Classification Name:	Controller, Foot, Handpiece And Cord
	Product Code:	EBW
	Regulation:	21 CFR 872.4200, Dental handpiece and accessories

5. 510(K) SUMMARY

Device Description:

The subject modified General Cutting Contra Handpiece (modified Ti-Max Z Series: Z10L, Z15L, Z25L, Z85L, Z95L) is a contra-angle dental handpiece powered by either an air-motor or electronic-micromotor for use in general dentistry. The modified General Cutting Contra Handpiece is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials, and removal of crowns and filling materials. The modified General Cutting Contra Handpiece transmits rotational force from the motor to the gears through a clutch. The allowable maximum speed for the motor is 40,000 min^{-1}. Then the rotation force reaches the chuck and the dental bur receives the rotation force. The dental bur cuts and grinds teeth using the rotation force. The rotation speed varies depending on the gear ratios as follows:

Z95L	1:5 Increasing
Z85L	1:5 Increasing
Z25L	1:1 Direct Drive
Z15L	4:1 Reducing
Z10L	16:1 Reducing

The modified General Cutting Contra Handpiece feature fiber optic providing illumination to the cutting area.

The subject of this Special 510(k) submission is an addition of the Switching Valve that allows to alternate between two types of water spray options: water spray (water + air) and water jet (water only) to the cleared device [K182999] to reduce the area of irrigation water splattering. This alternation is enabled using the Wrench accessory that has been previously cleared as a part of K121901. The coating material for the exterior of the handpiece has been changed from DURACOAT (Ti+MRK-T) to DURAGRIP (Ti+CrN). The coating material was previously used in the exterior of the nano Series of the predicate General Cutting Contra Handpiece [K182999] and has been cleared by FDA in 2019.

The original submission [K182999] included four series of contra handpieces: the S-Max M Series, the Ti-Max X Series, the Ti-Max Z Series, and the Ti-Max nano Series. The proposed modification applies solely to the Ti-Max Z series. The following models will be affected by this change: Z10L, Z15L, Z25L, Z85L, Z95L. The modified models are marked with “SW” on the neck on the handpiece.

The models that were cleared under the original General Cutting Contra Handpieces submission are not impacted by the present submission.

5. 510(K) SUMMARY

Indication for Use:

The Indication for Use statement is identical to the predicate device. The intended use of the modified device, as described in the labeling, has not changed as a result of the modification.

The General Cutting Contra Handpiece is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials.

Summary of Technological Characteristics:

Comparison with the predicate device shows the characteristics of the proposed modification (an addition of a switching valve in order to alternate between two types of water spray options: water spray (water + air) and water jet (water only)) to the modified General Cutting Contra Handpiece to be substantially equivalent to the predicate device.

	New Device	**Predicate Device**	**Reference Device**
Trade Name	**General Cutting Contra Handpiece**	**General Cutting Contra Handpiece**	**Ti-Max Z45**
510(k) Submitter [Number]	NAKANISHI INC. [TBD]	NAKANISHI INC. [K182999]	NAKANISHI INC. [K121901]
Product Code(s)	EGS	EGS	EGS
Indications for Use	The General Cutting Contra Handpiece is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.	The General Cutting Contra Handpiece is powered by either an air-motor or electronic micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials and removal of crowns and filling materials.	Ti-Max Z45 is powered by either an air-motor or electric micromotor for use in general dentistry. The device is intended for cutting and grinding teeth, cavity preparations, tooth and crown preparations, finishing and trimming teeth and filling materials, and removal of crowns and filling materials.
Application	General Dentistry	General Dentistry	General Dentistry
Model Numbers	Z10L, Z15L, Z25L, Z85L, Z95L	Z10L, Z15L, Z25L, Z85L, Z95L	Z45, Z45L
Weight	57g – 59.5g	57g – 59.5g	66.5 g

5. 510(K) SUMMARY

Burs	ISO 1797-1 (Type1) ISO 1797-1 (Type3)	ISO 1797-1 (Type1) ISO 1797-1 (Type3)	ISO 1797-1 (Type3) φ1.59-1.60mm FG Bur
Coupling Type	ISO 3964 (EN ISO 3964) Standard Coupling	ISO 3964 (EN ISO 3964) Standard Coupling	ISO 3964
Max Rotation Speed (motor)	40,000min^{-1} max	40,000min^{-1} max	40,000 min^{-1} max
Gear Ratio Max rotation speed (handpiece)	16:1 Reduction-2,500min^{-1} 4:1 Reduction-10,000min^{-1} 1:1 Direct Drive-40,000min^{-1} 1:5 Increasing-200,000min^{-1}	16:1 Reduction-2,500min^{-1} 4:1 Reduction-10,000min^{-1} 1:1 Direct Drive-40,000min^{-1} 1:5 Increasing-200,000min^{-1}	168,000 min^{-1}
Cleaners/ Lubricants	NSK PANA SPRAY Plus [K163483]	NSK PANA SPRAY Plus [K163483]	Cleaners: N/A Lubricants: NSK PANA SPRAY [K052700], NSK PANA SPRAY Plus [K131014], or NSK automatic handpiece cleaning and lubrication system [K081811]
Sterilization Method	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)	Steam Autoclave (Moist Heat)
Sterilization Standard	ISO 17665-1:2006	ISO 17665-1:2006	ISO 17665-1:2006

Summary of Performance Testing:

The fundamental scientific technology of the General Cutting Contra Handpiece has not been modified. The risks and hazardous impacts of the device modification were analyzed by FMEA methodology. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented as part of product design. The overall assessment concluded that all identified risks and hazardous conditions were successfully mitigated and accepted.

Testing confirmed that the General Cutting Contra Handpiece device complies with the applicable technical standards, internal specifications, and FDA guidance documents and is safe and effective for its intended use.

5. 510(K) SUMMARY

	Cleaning and sterilization validation testing presented in the predicate 510(k) clearance [K182999] is leveraged to demonstrate that the product continues to meet established performance requirements.
Biocompatibility Testing:	The biocompatibility testing was not repeated as the subject device is made from the same material, same manufacturing processes, and same packaging configuration as those utilized in the fabrication of both the predicate [K182999] and reference devices [K121901]. The biocompatibility testing conducted on the predicate and reference devices ensures that the modified General Cutting Contra Handpiece has a safe biocompatibility profile and is safe to use.
Discussion of the Clinical Tests:	Clinical testing was not required for a determination of substantial equivalence of the modified General Cutting Contra Handpiece.
Conclusion:	NAKANISHI INC. considers the modified General Cutting Contra Handpiece 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, materials, and established medical use.