August 19, 2021

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

Re: K211584
Trade/Device Name: Oral Surgery Contra
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: KMW
Dated: May 21, 2021
Received: May 24, 2021

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, 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)*
K211584

Device Name
Oral Surgery Contra

Indications for Use *(Describe)*
Oral Surgery Contra is for oral surgery. This device is driven by an electronic micromotor for oral surgery and dental implant. This device aims to transfer the rotation of the power source with various gear ratios, and moves instruments such as a surgical bur to cut the maxillary/mandibular bone during oral surgery treatment.

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

K211584

Submitter:	NAKANISHI INC. 700 Shimohinata Kanuma, Tochigi 322-8666 Japan	
Contact Person:	Mr. Masaaki Kikuchi General Manager, Regulatory Affairs Dept. TEL: +81-289-64-7277 FAX: +81-289-62-9738 email: m-kikuchi@nsk-nakanishi.co.jp	
Date Prepared:	August 16, 2021	
Submission Type:	Traditional 510(k)	
Subject Device:	Manufacturer:	NAKANISHI INC.
	Trade Name:	Oral Surgery Contra
	Common Name:	Handpiece, Rotary Bone Cutting
	Regulatory Class:	Class II
	Product Code:	KMW
	Regulation:	21 CFR 872.4120, Bone cutting instrument and accessories
Predicate Device:	Clearance:	K173905 dated June 19, 2018
	Manufacturer:	NAKANISHI INC.
	Trade Name:	Surgic Pro, Surgic Pro+
	Common Name:	Controller, Foot, Handpiece and Cord
	Regulatory Class:	Class I
	Classification Name:	Dental Handpiece and Accessories
	Product Code(s) - Primary:	EBW
	Product Code(s) – Subsequent	EGS KMW
	Regulation:	21 CFR 872.4200, Dental handpiece and accessories
Reference Device:	Clearance:	K161957 dated November 23, 2016
	Manufacturer:	W&H Dentalwerk Burmoos GmbH
	Trade Name:	Implantmed SI-1015 incl. Accessories
	Common Name:	Controller, Foot, Handpiece and Cord
	Regulatory Class:	Class I
	Classification Name:	Dental Handpiece and Accessories
	Product Code:	EBW
	Regulation:	21 CFR 872.4200, Dental handpiece and accessories

Device Description:

The Ti-Max Series Oral Surgery Contra handpieces, X-SG93L, X-SG93 and X-SG25L, are contra-angle handpieces that are intended for use by a clinician in a healthcare facility/hospital setting for oral surgery and preparation for dental implant operation. The subject handpieces are available in two options: 1) fiber optic glass (X-SG93L and X-SG25L) or 2) non-optic (X-SG93).

The Oral Surgery Contra handpieces are driven by a micromotor, thereby rotating surgical burs at different transmission gear ratios, to cut the maxillary/mandibular bone during oral surgery and preparation for dental implant surgery. The maximum rotational speeds of the handpieces are as follows: 120,000 min^{-1} for

the X-SG93L and X-SG93 models; 40,000 min-1 for the X-SG25L model. The maximum rotation speed depends on the transmission gear ratios as follows:

Model	Transmission gear ratio	Maximum speed
X-SG93L	1:3 Increasing	120,000 min^{-1}
X-SG93	1:3 Increasing	120,000 min^{-1}
X-SG25L	1:1 Direct Drive	40,000 min^{-1}

The handpieces are manufactured using titanium and stainless steel and feature a push-button chuck mechanism. They are designed for use with surgical motors with an ISO 3964 (EN ISO 3964) type coupling system.

The handpieces are designed for use with surgical burs, as follows:

- X-SG93L and X-SG93: ISO 1797 Type 3 FG burs (φ1.59 - 1.6 mm)
- X-SG25L: ISO 1797 Type 1 CA burs (φ2.334 - 2.35 mm).

The Oral Surgery Contra handpieces are a prescription-only device.

Indications for Use:

Oral Surgery Contra is for oral surgery. This device is driven by an electronic micromotor for oral surgery and dental implant. This device aims to transfer the rotation of the power source with various gear ratios, and moves instruments such as a surgical bur to cut the maxillary/mandibular bone during oral surgery treatment.

Summary of Technological Characteristics:

Comparison with the predicate device shows the characteristics of the subject device to be substantially equivalent to the predicate device. As such, the Oral Surgery Contra handpieces and the predicate device have the same technological characteristics:

- Intended use
- Method of operation
- Push-button autochuck
- Lubrication requirements
- Autoclavable

The following technological differences exist between the subject device and the predicate:

- Transmission gear ratios
- Compatible burs

These differences do not raise different questions of safety and effectiveness. Additionally, the reference device has the similar transmission ratios and is compatible with the same types of burs as the subject device.

510(k) SUMMARY

The following table summarizes the comparison of the subject Oral Surgery Contra handpieces with the primary predicate and reference devices for indications for use and technological characteristics.

	Subject Device	Predicate Device	Reference Device
Trade Name	**Oral Surgery Contra**	**Surgic Pro, Surgic Pro+**	**Implantmed SI-1015 incl. Accessories**
510(k) Submitter [Number]	NAKANISHI INC. [K211584]	NAKANISHI INC. [K173905]	W&H Dentalwerk Bürmoos GmbH [K161957]
Product Code(s) - Primary	KMW	EBW	EBW
Product Code(s) - Subsequent	n/a	KMW EGS	n/a
Indications for Use	Oral Surgery Contra is for oral surgery. This device is driven by an electronic micromotor for oral surgery and dental implant. This device aims to transfer the rotation of the power source with various gear ratios, and moves instruments such as a surgical bur to cut the maxillary/mandibular bone during oral surgery treatment.	<u>Surgic Pro+ / Surgic Pro</u> The Surgic Pro+ / Surgic Pro is intended for use in dental oral surgery and dental implant. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth. <u>SG20/ X-SG20L</u> This medical device is for oral surgery and dental implant operation. This device is driven by an electronic micromotor for oral surgery and dental implant. The device is intended to transmit the rotation of the power source at different gear ratios, thereby moving instruments such as surgical burs or surgical drills to cut the maxilla / mandible during oral surgery and dental implant.	Mechanical drive unit with coolant supply for transmission instruments with ISO 3964 (DIN13940) compatible coupling system, for use in dental surgery, implantology and maxillofacial surgery (CMF) for treatment of dental hard tissue.
Application	Dental Oral Surgery Preparation for Dental Implants	Dental Oral Surgery Dental Implants	Dental Surgery Implantology Maxillofacial Surgery (CMF)

510(k) SUMMARY

Model Numbers	X-SG25L X-SG93 X-SG93L	SG20 X-SG20L	WS-56 L WS-75 L WS-91 L WS-92 L S-11 L
Power Source	Electrical Micromotor	Electrical Micromotor	Electrical Micromotor
Handpiece Chuck Mechanism	Push-button	Push-button	Push-button
Burs	ISO 1797 Type 1 CA X-SG25L ISO 1797 Type 3 FG X-SG93 X-SG93L	ISO 1797-1 (Type 1)	ISO 1797-1 Type 1 WS-56 L WS-75 L ISO 1797-1 Type 3 WS-91 L WS-92 L ISO 1797-1 Type 2 S-11 L
Handpiece Coupling	ISO 3964 (EN ISO 3964)	ISO 3964 (EN ISO 3964)	ISO 3964 (EN ISO 3964)
Transmission ratio	X-SG93L = 1:3 Increasing X-SG93 = 1:3 Increasing X-SG25L = 1:1 Direct Drive	SG20 = 20:1 Reduction X-SG20L = 20:1 Reduction	WS-56 L = 1:1 WS-75 L = 20:1 WS-91 L = 1:2.7 WS-92 L = 1:2.7 S-11 L = 1:1
Materials Composition (Handpiece and Exterior Coating)	Pure Ti(MIM)+MRK-T	SG20: Stainless Steel + CrN X-SG20L: Pure Ti(MIM)+MRK-T)	Chromium coated steel and chromium coated brass
Cleaning	Automatic Cleaning (Washer-Disinfector) Or Manual Cleaning	Automatic Cleaning (Washer-Disinfector) Or Manual Cleaning	Automatic Cleaning (Washer-Disinfector) Or Manual Cleaning
Sterilization	Pre-Vacuum (Dynamic Air Removal) 132°C, 4 min. Drying Time: 30 min. Gravity Displacement 132°C, 15 min Drying Time: 30 min	Pre-Vacuum (Dynamic Air Removal) 132°C, 4 min. Drying Time: 30 min. Gravity Displacement 132°C, 15 min Drying Time: 30 min	Pre-Vacuum 132°C, 4 min Gravity Displacement 132°C, 15 min

Summary of Performance Testing:

The Oral Surgery 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. 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." Documentation was provided demonstrating that the Oral Surgery Contra 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.* In addition, testing for conformity to ISO 14457:2012; "Dentistry – Handpieces and Motors" has been conducted.
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 ISO 10993-5 • Sensitization per ISO 10993-10 • Irritation per ISO 10993-10 • Acute Systemic Toxicity per ISO 10993-11 • Pyrogenicity per ISO 10993-11
Discussion of the Clinical Tests:	Clinical testing was not required for a determination of substantial equivalence of the Oral Surgery Contra.
Conclusion:	NAKANISHI INC. considers the Oral Surgery Contra handpieces to be substantially equivalent to the predicate and reference devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design and established medical use.