Nakanishi Inc.
% Ms. Katie Reneson
Regulatory Specialist
Ken Block Consulting
800 East Campbell Road, Suite 202
Richardson, Texas 75081

June 19, 2018

Re: K173905
Trade/Device Name: Surgic Pro, Surgic Pro+
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EBW
Dated: May 29, 2018
Received: May 31, 2018

Dear Katie Reneson:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173905

Device Name
Surgic Pro+ / Surgic Pro

Indications for Use *(Describe)*

Surgic Pro+ / Surgic Pro

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.

SG20/ X-SG20L

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) SUMMARY

Submitter:	NAKANISHI INC. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666
Contact Person:	Mr. Kimihiko Satoh General Manager, Regulatory Affairs, R&D Division TEL: +81-3-5828-7716 FAX: +81-3-5828-0064 k-satoh@nsk-nakanishi.co.jp
Date Prepared:	May 29, 2018
Trade Name:	*Surgic Pro+ / Surgic Pro*
Common Name:	Controller, Foot, Handpiece And Cord Handpiece, Rotary Bone Cutting Handpiece, Contra- And Right-Angle Attachment, Dental
Classification Name:	Dental handpiece and accessories.
Regulation:	21 CFR 872.4120 Class II
Product Code:	EBW, KMW, EGS
Predicate Device:	K161957 W&H Implantmed SI-1015

Device Description:

The *Surgic Pro+ / Surgic Pro* consists of the Control Unit, the Foot Control, Micromotor, Handpiece, and accessories for use with specific Motors. Components and accessories are included with each series set in accordance to the client's specific needs and requirements. The Control Unit drives the Motors during procedures and is used to control the functions related to the Motor such as rotational direction. The Control Unit is available without data storage capability or USB REC Key and USB flash drive socket for the *Surgic Pro* and with data storage capability and USB REC Key and USB flash drive socket for the *Surgic Pro+*. The *Surgic Pro+* has the same features as *Surgic Pro* with the addition of the USB data storage system.

The Handpieces included within this submission are intended for use in 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. Available Handpieces include Optic Ti-Max X-SG20L and Non-Optic S-Max SG20. Optic and non-optic contra angle Handpieces are available to be used with the Motors to ensure torque accuracy. The Handpieces are designed for use with surgical burs that are φ2.35mm and conform to Type 1 of ISO 1797-1 (EN ISO 1797) standard.

Two models of the Micromotor with Motor cord are available, SGL70M Optic Motor and SG70M Non-Optic Motor. The SGL70M Optic Motor contains LED illumination of over 32,000 LUX.

The Foot Control allows operation of all functions within the preset parameters without touching the control panel to avoid accidental activation of the Micromotor

NAKANISHI INC. Headquarters : 700 Shimohihata Kanuma-shi Tochigi 322-8666, Japan
www.nsk-inc.com Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan

outside the present limit. The Foot Controller provides the user with "hands-free" control of the coolant flow, program selection, forward/reverse rotational direction selection, and speed during operation.

Indications for Use:

Surgic Pro+ / Surgic Pro

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.

The SG20 and X-SG20L

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.

Summary of Technological Characteristics:

The *Surgic Pro+ / Surgic Pro* is an AC-electrically powered dental surgical system that powers and controls the functions of the compatible handpiece attachments. The software allows for the control of the device features such as brightness, coolant flow, rotational direction, gear ratio, device programming, calibration, speed, torque, data recording, and sound volume. The proposed device shares technological characteristics with the predicate devices. The proposed device also has some differences in technological characteristics from those of the predicate devices. Any differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences and do not impact the substantial equivalence of the device.

	Proposed Device: NAKANISHI Inc. [K173905]	**Predicate Device: W&H [K161957]**
Trade Name	Surgic Pro+ Surgic Pro	Implantmed SI-1015
Indication for Use	Surgic Pro+ / Surgic Pro 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. SG20/ X-SG20L 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.
Package Contents	Control Unit Micromotor (Optic or Non-Optic) Foot Controller Handpiece (Optic or Non-Optic) Irrigation tube (5 pcs) Operation Manual	Control Unit Micromotor Foot Controller (wired or wireless) Irrigation Tube Operation Manual
Memory	8 Pre-set implant systems 8 user defined of 8 steps each	5 programs for various stages of implantology. Programs 1-3 are for adjusting speed and programs Programs 4-5 are adjusting the torque

NAKANISHI INC.
www.nsk-inc.com
Headquarters : 700 Shimohihata Kanuma-shi Tochigi 322-8666, Japan
Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan

Data Storage Output	USB .csv and .bmp formats	USB .csv and .pdf formats
Micromotor Torque	5 - 80Ncm	5 - 80Ncm
Micromotor Rotation Speed Range	200-40,000 min^{-1}	200-40,000 rpm
Handpiece Coupling	ISO 3964	ISO 3964
Handpiece Chuck Mechanism	Push-button	Push-button
Bur	Ø 2.35mm/ Type 1 (ISO 1797)	Ø 2.35mm/ Type 1 (ISO 1797)
Foot Control Degree of Protection	IPX8	IPX8

Performance Testing:

The *Surgic Pro+ / Surgic Pro* was developed and is 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 handpiece 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 *Surgic Pro+ / Surgic Pro* 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 evaluations were selected in accordance with AAMI/ANSI/ISO 10993-1: "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". Documentation was provided demonstrating compliance of the *Surgic Pro+/Surgic Pro* to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards. Electrical safety was conducted and performed in accordance with IEC 60601-1. In addition, testing for conformity to ISO standard 14457 has been conducted.

Conclusion:

NAKANISHI INC. considers the *Surgic Pro+ / Surgic Pro* to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in intended use, principals of operation, functional design, and established medical use.

NAKANISHI INC.
www.nsk-inc.com
Headquarters : 700 Shimohihata Kanuma-shi Tochigi 322-8666, Japan
Tokyo Office : MY Building 1-13-3 Ueno Taito-ku Tokyo 110-0005, Japan