June 20, 2024

Nakanishi Inc.
Mr. Satoru Ikeda
Regulatory Affairs Department
TIX TOWER UENO 9F
4-8-1, Higashiueno
Taito-ku, Tokyo 110-0015
JAPAN

Re: K233117
Trade/Device Name: Surgic Pro2 (Surgic Pro2 OPT), Surgic Pro2 (Surgic Pro2 NON-OPT)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: May 21, 2024
Received: May 21, 2024

Dear Satoru Ikeda:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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.

Submission Number *(if known)*

K233117

Device Name

Surgic Pro2 (Surgic Pro2 OPT);
Surgic Pro2 (Surgic Pro2 NON-OPT)

Indications for Use *(Describe)*

The Surgic Pro2 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.

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) #: K233117

510(k) Summary

Prepared on: 2024-06-20

Contact Details

21 CFR 807.92(a)(1)

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Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Surgic Pro2 (Surgic Pro2 OPT); Surgic Pro2 (Surgic Pro2 NON-OPT)
Common Name	Dental handpiece and accessories
Classification Name	Controller, Foot, Handpiece And Cord
Regulation Number	872.4200
Product Code	EBW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173905	Surgic Pro+ / Surgic Pro	EBW
K161957	W&H Implantmed SI-1015 Incl. Accessories	EBW
K161213	XSmart iQ	EBW

Device Description Summary

21 CFR 807.92(a)(4)

The Surgic Pro2 consists of the Control Unit, the Foot Control, Motor and accessories. The Control Unit drives the Motors during procedures and is used to control the functions related to the Motor such as rotational direction. The Foot Control provides the user with "hands-free" control of the coolant flow, program selection, forward/reverse rotational direction selection, and speed during operation. Two models of the Motor with Motor cord are available, SGL80M Optic Motor and SG80M Non-Optic Motor. The SGL80M Optic Motor

contains LED illumination of over 32,000 LUX. Each Motor is included with each series set in accordance to the client's specific needs and requirements.
The Surgic Pro2 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.
Features of this product are Bluetooth connectivity with a Foot Control, "Osseo 100+" ISQ measurement device *, and other company's products "iPad". The ISQ values measured by the "Osseo 100+" can be displayed on the Surgic Pro2 control unit. The "iPad" can display information on the control unit including ISQ values on the dedicated application for Surgic Pro2. The displayed information can be stored in the iPad.
* The ISQ value is measured by the Osseo100+ and the ISQ value displayed on the Osseo100+ is shown on the display of the SurgicPro2 connected via Bluetooth.
The product is provided unsterilized, and the motors are washed and sterilized at a medical institution, and used repeatedly. The product has no bio-contact components.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Surgic Pro2 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Both the Indications for Use for the subject device and the Indications for Use for the predicate device are intended for dental applications, including dental oral surgery and dental implant.
The only difference between the Indications for Use is the Device Name

Technological Comparison

21 CFR 807.92(a)(6)

The Surgic Pro2 is an AC-electrically powered dental surgical system that transmits power to compatible handpieces and controls their functions. The software allows for the control of the device features such as brightness, coolant flow, rotation direction, program selection, calibration, speed, torque, and sound volume. Surgic Pro2 also provides Foot Control and connection to external devices via a Bluetoothe connection. The subject device shares these technical characteristics with the predicate and reference devices.
The proposed device also has some differences in technological characteristics from those of the predicate and reference devices. These differences are only minor, such as basic shape, structure, Bluetooth version, and removal of some accessories, and reflect user preferences, market strategies, and version updates, and do not affect the substantial equivalence of the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

For Surgic Pro2, the following non-clinical tests were performed to support substantial equivalence of the subject device.
Performance Test:
The Surgic Pro2 subject instrument was subjected to verification and validation testing for motor performance, reprocessing, software, electrical safety, EMC, and cybersecurity to support substantial equivalence. The results of these tests demonstrate compliance with the requirements of the following standards and guidance.

- ISO 14457:2017 "Dentistry - Handpieces and motors"
- 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"
- ISO 17664-1:2021 "Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices"
- ISO 17664-2:2021 "Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Non-critical medical devices."
- IEC 62304:2006+AMD1:2015 "Medical device software - Software life cycle processes"
- IEC 60601-1:2005+AMD1:2012+AMD2:2020 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- IEC 60601-1-2:2014 "Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"
- IEEE/ANSI C63.27:2021 "American National Standard forEvaluation of Wireless Coexistence"
- AAMI TIR57:2016 "Principles for medical device security - Risk management"
- IEC 81001-5-1:2021 "Health software and health IT systems sfety, effectiveness and security - Part 5-1:Security - Activities in the procuct life cycle"
- FDA guidance document "Dental Handpieces - Premarket Notification [510(k)] Submissions"
- FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling"
- FDA guidance document "Content of Premarket Submissions for Device Software Functions"

• FDA guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"

Biocompatibility:

No biocompatibility test was required to support the substantial equivalence of the Surgic Pro2."

The performance test results support the substantial equivalence of the subject Surgic Pro2 to the precedent device.