May 21, 2021

MICRO-NX Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K201192
Trade/Device Name: Impla-NX (Model: ISE-270M)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: May 14, 2021
Received: May 19, 2021

Dear Priscilla Chung:

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: December 31, 2013
*See PRA Statement on last page.*

510(k) Number *(if known)*

Device Name
Impla-NX (Model: ISE-270M)

Indications for Use *(Describe)*

The Impla-NX (Model: ISE-270M) 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)

**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

**(**K201192)

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: May 3, 2021

**1. 510K Applicant / Submitter:**

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**1. Submission Contact Person**

LK Consulting Group USA, Inc.
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Priscilla Chung
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**2. Device**

- Proprietary Name – Impla-NX (Model: ISE-270M)
- Common Name – Implant Surgical Engine
- Classification Name - Dental handpiece and accessories
- Classification – 21CFR 872.4200 (Product Code: EBW)

**3. Predicate Device**

- Surgic Pro by NSK Nakanishi, Inc (K173905)

**4. Description:**

As an engine to operate and control handpiece used for dental implant surgery, this device is composed of main body, BLDC motor and foot control.
With external power supply being provided, this device operates the main body through switching AC power to DC power and it performs dental implant surgery with handpiece being connected for rotation power generated through turning BLDC motor.

## 8. Indications for Use

The Impla-NX (Model: ISE-270M) 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.

## 9. Substantial Equivalence Discussion:

The Impla-NX (Model: ISE-270M) is substantially equivalent to Surgic pro( K173905) in the indications for use and the technological characteristics. The following comparison table is presented to demonstrate substantial equivalence.

The Impla-NX (Model: ISE-270M) does not have new Indications for Use; it is the same as the predicate device's indications for use. It shows equivalent specifications with the predicate devices in most of parameters.

The difference between the subject device and the predicate device is the number of memory set but this does not affect the performance as it is just for user convenience. The user can always adjust the setting parameters as needed.

Another difference is the torque of motor that the subject device has a slightly lower max torque than the predicate device. However, the max torque of 70Ncm is more than enough to be used in the clinical setting for the Indications for Use and it is covered by the max value of the predicate device; therefore, it would not raise a question in safety.

We conclude that the subject device is substantially equivalent to the predicate device.

| | **Subject Device** | **Predicate Device** | **Comparison** |
|---|---|---|---|
| **510(k) Number** | K201192 | K173905 | - |
| **Device Name** | Impla-NX (Model: ISE-270M) | Surgic Pro | - |
| **Common Name** | Controller, Foot, Handpiece and cord | Controller, Foot, Handpiece And Cord | - |
| **Manufacturer** | MICRO-NX Co., Ltd. | NSK Nakanishi, Inc | - |
| **Indications for Use** | The Impla-NX (Model: ISE-270M) is intended for use in dental oral surgery and dental | The Surgic Pro+ / Surgic Pro is intended for use in dental oral surgery and dental implant. | Same |

| | | | |
|---|---|---|---|
| | 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 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. | |
| **Micromotor drive** | Electric<br><br>Micromotor drive | Electric<br><br>Micromotor drive | Same |
| **Package contents** | Control Unit<br>Micromotor<br><br>Foot switch(wired)<br>Irrigation Tube<br>Operation Manual | Control Unit<br>Micromotor<br><br>Foot Controller<br>Handpiece<br><br>Irrigation tube<br>Operation Manual | Different<br><br>- The subject device does not include handpieces. |
| **Optic** | Yes | Yes | Same |
| **Memory** | ▪ 6 Pre-set implant systems<br><br>▪ 9 user defined of 9 steps each | ▪ 8 Pre-set implant systems<br><br>▪ 8 user defined of 8 steps each | Different |
| **Torque on the motor** | Max.70Ncm | Max.80Ncm | Same<br><br>- It is within the control range of the predicate product. |
| **Speed on the motor** | 200-40,000 rpm | 200-40,000 rpm | Same. |
| **Conformance with standards for shanks** | E-type(ISO3964) | E-type(ISO3964) | Same |

**10. Performance Tests (Non-clinical)**

Non-clinical bench tests were performed as followings:

- ISO 3964 Dental Handpieces - Coupling dimensions

- ISO 7494-1 Dentistry - Dental units -Part 1: General requirements and test methods
- ISO 14457:2017 Dentistry - Handpieces and motors
- ISO 17665-1, 2 – Steam Sterilization Validation
- IEC 60601-1, IEC 60601-1-2: Electrical safety and EMC
- IEC 80601-2-60: Particular Requirements For The Basic Safety And Essential Performance Of Dental Equipment
- IEC 62471 Photobiological safety of lamps and lamp systems

Along with the above tests, sterilization validation, and software validation were also conducted. None of the testing demonstrated any design characteristics that violated the requirements of the standards or resulted in any safety hazard.

## 10. Conclusions:

Based on the information provided in this premarket notification, MICRO-NX Co., Ltd. concludes that the Impla-NX (Model: ISE-270M) is substantially equivalent to the predicate device as described herein in safety and effectiveness.