July 18, 2025

Micro-NX Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc
18881 Von Karman Ave STE 160
Irvine, California 92612

Re: K231562
Trade/Device Name: ELEC ENGINE (Model: ISE-170L)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: June 17, 2025
Received: June 20, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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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OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K231562

Device Name
ELEC ENGINE (Model: ISE-170L)

Indications for Use *(Describe)*

The ELEC ENGINE (Model: ISE-170L) 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)*

K231562 - 510(k) Summary

Date: July 15, 2025

1. 510K Applicant / Submitter:

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Republic of Korea
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2. Submission Contact Person

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3. Device

- Proprietary Name – ELEC ENGINE™ (Model: ISE-170L)
- Common Name – Implant Surgical Engine
- Classification Name - Dental handpiece and accessories
- Classification – 21CFR 872.4200 (Product Code: EBW)

4. Predicate Device

- Proprietary Name – Impla-NX (Model: ISE-270M) by MICRO-NX CO., LTD. (Model: ISE-270M)
- 510k# - K201192
- Common Name – Implant Surgical Engine
- Classification Name - Dental handpiece and accessories
- Classification – 21CFR 872.4200 (Product Code: EBW)

5. 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.

6. Indications for Use

The ELEC ENGINE™ (Model: ISE-170L) 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.

7. Substantial Equivalence Discussion:

The ELEC ENGINE™ (Model: ISE-170L) is substantially equivalent to (Model: ISE-270M & ISE-270C) in the indications for use and the technological characteristics. The following comparison table is presented to demonstrate substantial equivalence.

The ELEC ENGINE™ (Model: ISE-170L) does not have new intended use; it is the same as the predicate device's indications for use. It shows equivalent specifications with the predicate devices in all of the parameters.

The differences between the subject device and the primary predicate device include changes in button shape and location, foot switch color, irrigation tube size, max. coolant flow rate, housing design and bolt size.

These differences are not significant since they do not raise any new or potential safety risks to the user or patient. Based on the test results submitted in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

	Candidate Device	**Predicate Device**	**Comparison**
510(k) Number	K231562	K201192	-
Device Name	**ELEC ENGINE™** (Model: ISE-170L)	Impla-NX (Model: ISE-270M & ISE-270C)	-
Common Name	Controller, Foot, Handpiece and cord	Controller, Foot, Handpiece and cord	-
Manufacturer	MICRO-NX Co., Ltd.	MICRO-NX Co., Ltd.	-
Intended Use	**ELEC ENGINE™** (Model: ISE-170L) 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 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.	Same

Micromotor drive	Electric Micromotor drive	Electric Micromotor drive	Same
Package contents	Control Unit Micromotor Foot switch(wired) Irrigation Tube Operation Manual	Control Unit Micromotor Foot switch(wired) Irrigation Tube Operation Manual	Same
Optic	Yes	Yes	Same
Memory	▪ 6 Pre-set implant systems ▪ 9 user defined of 9 steps each	▪ 6 Pre-set implant systems ▪ 9 user defined of 9 steps each	Same
Torque on the motor	Max.70mNcm	Max.70Nmcm	Same
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

8. Performance Tests (Non-clinical)

Verification, validation and testing activities were conducted to establish the performance, functionality and reliability characteristics of the modified devices. The device passed all the tests based on pre-determined Pass/Fail criteria. Testing was performed on the subject device in accordance with the following standards:

- Electrical and Mechanical Safety Testing: IEC 60601-1, IEC 60601-1-2, and IEC 80601-2-60
- Reprocessing Validation: ISO 17664-1 and ISO 17665-1
- Biocompatibility Testing: ISO 10993-1, ISO 10993-5, ISO 10993-23, ISO 10993-10
- Performance Testing: ISO 14457
- Usability Testing: IEC 60601-1-6 and IEC 62366-1

9. Conclusions:

Based on the information provided in this premarket notification, MICRO-NX Co., Ltd. concludes that the ELEC ENGINE™ (Model: ISE-170L) is substantially equivalent to the predicate device as described herein in safety and effectiveness.