February 7, 2022

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

Re: K201191
Trade/Device Name: ELEC-LED
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: November 9, 2021
Received: November 12, 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.Ch.E.
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)*
K201191

Device Name
ELEC-LED

Indications for Use *(Describe)*

The ELEC-LED is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.

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

(K201191)

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

Date: February 3, 2022

1. 510K Applicant / Submitter:

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2. Submission Contact Person

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2. Subject Device

- Proprietary Name –ELEC-LED
- Common Name – Motor Handpiece Control Unit
- Classification Name –Dental Handpiece and Accessories
- Product Code – EBW
- Classification Regulation - 21 CFR 872.4200

3. Predicate Device

- Optima MX INT by Bien air Dental SA (K042759)

4. Description:

This product consists of a micro motor, motor controller and display panel. Receiving rated input of AC 24V, this device controls motor speed, and spinning direction through the motor control circuit inside the controller. Motor speed, motor operating mode, light and spinning direction functions can be set on the display panel. The operating mode of the motor is composed of three modes: HD (Hand control mode), PP (Press pedal mode) and EP (Electric

pedal mode).

5. Indications for Use

The ELEC-LED is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output from a dental treatment center.

6. Substantial Equivalence Discussion:

The subject device is substantially equivalent to Optima MX INT SI0915/923(K042759). The subject device has the same indications for use and the technological characteristics as the predicate device. It also has the equivalent specifications as the predicate device in almost all parameters. The major difference is that the subject device offers a model without water and air spray hoses, and also a model without LED. However, these differences do not raise a question in substantial equivalence discussion since the user can use water and air spray hoses that are usually provided on a dental chair, and lighting system in the dental office. Since these are optional features, we believe these differences do not raise a concern for substantial equivalence. Based on the comparison and the performance test data, we conclude that the subject device is substantially equivalent to the predicate device.

	Subject Device	**Predicate Device**	**Comparison**
510(k) Number	K201191	K042759	-
Device Name	ELEC-LED (EL-B40S, EL-B40L, EL-B40M, EL-B40I)	Optima MX INT	-
Manufacturer	MICRO-NX Co., Ltd.	Bien air Dental SA	
Intended Use	The ELEC-LED is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output form a dental treatment center.	The Optima MX is intended for use in dentistry for restoration, prophylaxis and endodontic procedures. It provides control for motorized dental handpieces by converting pneumatic output form a dental treatment center.	Equivalent

Micromotor type	Brushless, internal coolant air	Brushless, internal coolant air	Identical
Device components	Control unit with hose and electrical motor	Control unit with hose and electrical motor	Identical
Power supply voltage	AC 24V	AC 24V	Identical
Speed on the motor	1,000-40,000 rpm	100- 40,000 rpm	Equivalent
Max. Torque	3Ncm	3Ncm	Identical
Rotation direction	clockwise / counterclockwise	clockwise / counterclockwise	Identical
Spray Air Pressure	2.5bar	2.5bar	Identical
Spray Water Pressure	2bar	2bar	Identical
Irrigation system	1) EL-B40S, EL-B40S, EL-B40I(Irrigation system, motor cooling air) 2) EL-B40M (only motor cooling air)	Irrigation and motor Cooling air	The EL-B40M type does not have water injection function, therefore, there is no water and air spray hoses. The user can use water and air spray hoses that are usually provided on a dental chair.
Light(Motor LED)	1) Yes (EL-B40S, EL-B40L) 2) No (EL-B40I, EL-B40M)	Yes	The subject device has both a model with an LED and a model without LED; however, since this product is used in a dental office which will be likely to have lighting system, it does not pose any risk.
Conformance with standards for shanks	Comply with ISO 3964	Comply with ISO 3964	Identical
Rotation	Clockwise, Counterclockwise	Clockwise, Counterclockwise	Identical

7. Performance Tests (Non-clinical)

Non-clinical bench tests were performed as followings:

- ISO 3964:2016 Dental Handpieces - Coupling dimensions
- ISO 7494-1:2011 Dentistry - Dental units -Part 1: General requirements and test methods
- ISO 14457:2017 Dentistry - Handpieces and motors
- IEC 60601-1, IEC 62366-1, IEC 60601-1-2: Electrical safety and EMC
- IEC80601-2-60:2012: Particular Requirements For The Basic Safety And Essential Performance Of Dental Equipment
- IEC 62366: Application of usability engineering to medical devices
- ANSI AAMI ST79:2017, ISO 17665-1, and ISO TS 17665-2: Sterilization validation

Software documentation for software of moderate level of concern per the FDA Guidance Document for Software Contained in Medical Devices was provided . The test results support that the subject device is substantially equivalent to the predicate device.

Cleaning and Sterilization validation for the motor and motor cable was provided per the FDA Guidance Document for Reprocessing of Medical Device.

Biocompatibility testing (cytotoxicity, sensitization, and oral mucosa irritation) for the direct and indirect patient contacting components was provided per the FDA Guidance Document for the Use of ISO 10993-1.

8. Conclusions:

Based on the information provided in this premarket notification, MICRO-NX Co., Ltd. concludes that the ELEC-LED is substantially equivalent to the predicate device as described herein in.