May 5, 2023

Mgnewton Ltd.
% Priscilla Chung
Official Correspondent
LK Consulting Group USA, Inc.
1150 Roosevelt, Suite 200
Irvine, California 92620

Re: K202963
Trade/Device Name: ELEC Master, ELEC Master Dual
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: April 7, 2023
Received: April 7, 2023

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,

Bobak Shirmohammadi -S

For Michael Adjodha, M.ChE.,CQIA
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202963

Device Name
ELEC Master & ELEC Master Dual

Indications for Use *(Describe)*

ELEC Master & ELEC Master Dual are intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment.

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) Summary K202963

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

Date: SEP 29, 2020

1. 510K Applicant / Submitter:

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2. Submission Contact Person

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Priscilla Chung
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3. Subject Device

-. Trade Name : ELEC Master & ELEC Master Dual
-. Classification Name : Controller, Foot, Handpiece and Cord
-. Regulation Number : 21 CFR 872.4200
-. Regulation Name : Dental handpiece and Accessories
-. Regulatory Class : I
-. Product Code : EBW

4. Predicate Device

-. Trade Name : A-dec NLZ electric motor system
-. 510(k) Number : K163131
-. Regulation Number : 21 CFR 872.4200
-. Regulation Name : Dental handpiece and Accessories
-. Regulatory Class : I
-. Product Code : EBW

5. 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 rotation direction through the motor control circuit inside the controller. Motor speed, light and rotation direction functions can be set on the display panel.

Micromotor Model Name	ELEC Master	ELEC Master Dual
Optic(White LED)	O	O
Torque	Max. 3Ncm	Max. 3Ncm
Number of motor(EML40W)	1	2
RPM(Gear 1: 1)	Max. 40,000	Max. 40,000

Direction	Clock / counter clock	Clock / counter clock

6. Indications for Use

ELEC Master & ELEC Master Dual are intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment.

7. Substantial Equivalence Discussion:

The subject device is substantially equivalent to A-dec NLZ electric motor system (K163131). 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 spray air pressure & spray water pressure. However this 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 in the dental office. Since these are optional features, we believe these differences do not raise a new question in safety and effectiveness. Based on the performance test data, we conclude that the subject device is substantially equivalent to the predicate device.

	Candidate Device	**Predicate 1**	**Comparison**
510(k) Number	K202963	K163131	-
Device Name	ELEC Master ELEC Master Dual	A-dec NLZ electric motor system	-
Manufacturer	MGNEWTON Ltd.	NAKANISHI INC.	
Indications for Use	ELEC Master & ELEC Master Dual are intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment.	A-dec NLZ electric motor system is intended for use in general dental applications such as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment.	Substantially Equivalent
Drive	Electronic-micromotor	Electronic-micromotor	Substantially Equivalent
Device components	Control unit with hose and electrical motor	Control unit with hose and electrical motor	Substantially Equivalent
Light (Motor LED)	Yes	Yes	Substantially Equivalent
Range of rotation speed	1,000-40,000 rpm	1,000- 40,000 rpm	Substantially Equivalent
Rotation Direction	Forward and Reverse	Forward and Reverse	Substantially Equivalent
Max. Torque	3Ncm	3Ncm	Substantially Equivalent
Spray Air Pressure	44 psi (0.3 MPa)	29psi (0.2 MPa)	Different #1
Spray Water Pressure	22 psi (0.15 MPa)	29psi (0.2 MPa)	Different #2
Coolant mechanism	Coolant air	Coolant air	Substantially Equivalent

Sterilization	Sterilized by user (Steam Sterilization)	Sterilized by user (Steam Sterilization)	Substantially Equivalent
Conformance with standards for shanks (Available Handpiece Type)	E-type Comply with ISO 3964	E-type Comply with ISO 3964	Substantially Equivalent

8. 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 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

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.

9. Conclusions:

Based on the information provided in this premarket notification, MGNEWTON Ltd. concludes that the ELEC Master & ELEC Master Dual are substantially equivalent to the predicate device as described herein in safety and effectiveness.