July 29, 2022

Micro-NX Co., Ltd.
% Seohee Kwon
RA Manager
K-Bio Solutions
201 South 4th Street, Suite 727
San Jose, California 95112

Re: K220577
Trade/Device Name: Dental Handpiece, Model CA160, CA160L, and CA500L
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EGS
Dated: May 10, 2022
Received: May 17, 2022

Dear Seohee Kwon:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220577

Device Name
Dental Handpiece

Indications for Use *(Describe)*
The Dental Handpiece with models of CA160, CA160L, and CA500L are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, and restorations for polishing teeth.

The Dental Handpiece is designed for use by a trained professional in the field of general dentistry.

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 K220577

Pursuant to Section 510(k) of Chapter V of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807, Title 21 of the Code of Federal Regulations, MICRO-NX Co., Ltd. submits the following information as premarket notification for the proposed device, Dental Handpiece with models of CA160, CA160L, and CA500L.

I. SUBMITTER

510(k) Correspondent: Seohee Kwon
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Manufacturer Contact: Sojeong Park (sojeong@micronx.co.kr)
Date Prepared: May 10th, 2022

II. SUBMISSION DEVICE

- Trade Name: Dental Handpiece
- Common Name: Handpiece, dental
- Classification Name: Dental handpiece and accessories
- Regulation Number: 21 CFR 872.4200
- Regulation Name: Dental handpiece and accessories
- Product Code: EGS
- Review Panel: Dental
- Regulatory Class: Class I
- Traditional 510(k) Registration

Prior formal correspondence with the FDA resulted in the 510(k) clearance of the Micro-NX Dental Handpiece(K192809) with models of SG200, SG200L, SA100L, SA100R, CA100L, and CA100R.

III. PREDICATE DEVICES

- Predicate Device: Dental Handpiece (K192809), Manufacturer: Micro-NX Co., Ltd.

IV. DEVICE DESCRIPTION

The intended use of the Dental Handpiece with models of CA160, CA160L, and CA500L are the same as the intended use of the predicate (K192809), model CA 100L and CA100R.

- Dental Handpiece with models of CA160, CA160L, and CA500L are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. Dental Handpiece is designed for use by a trained professional in the field of general dentistry.

- Predicate Dental Handpiece (K192809) with models of CA100L and CA100R are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. Dental Handpiece is designed for use by a trained professional in the field of general dentistry.

Dental Handpiece with the model CA160, CA160L and CA500L consists of the main body of the handpiece, which is used for transmitting rotational force for the general dental treatments. The torque transmitted from a wired electric micro-motor gets further transmitted to the joint part of Dental Handpiece. The rotational force is then decelerated according to the speed reducer of the gear which is transmitted to the head of the dental handpiece. The rotational force is transmitted under the permitted rotation mechanism.

Model CA160, CA160L and CA500L
All components of the Model CA160, CA160L and CA500L are the same as the predicate model CA100L and CA100R (K192809) with containing the main body and spray adapter. Model CA160, CA160L and CA500L can be connected to spray adapter (accessory component) which is used for channeling water and air for further applications to the dental treatments. The only difference between model CA160 and CA160L is that the CA160L has lighting function.

The component allocations of the proposed models of Dental Handpiece are provided in Table IV-1 below.

Table IV-1 Proposed device Model and Component Specification

Model	CA160	CA160L	CA500L
Main Body	**X**	**X**	**X**
Spray Adapter	**X**	**X**	**X**

The four product codes and models of Dental Handpiece are CA160, CA160L, and CA500L. The component names and functional descriptions for critical components of Dental Handpiece are provided in Table IV-2below.

Table IV-2. Component Names and Functional Descriptions for Critical Components of Dental Handpiece: CA160, CA160L, CA500L

Component Name	Function
Components of Handpiece Model CA500L	
Spindle Assembly	Receives torque from Middle Gear Assembly and transmits torque to final dental bur
Middle Gear Assembly	Transmitting the rotational force from the Inner Handle Assembly and delivers the rotational force to the Spindle Assembly
Button Assembly	Button for removal and attachment of the hand piece head
Head Cap	Case that wraps the Spindle Assembly. Head Cap is assembled with Button Assembly and Middle Gear Assembly
Head Assembly	The component that is assembled Spindle Assembly, Middle Gear Assembly, Button Assembly, Head Assembly
Joint Gear Assembly	Transmits the torque received from the motor to the Head Assembly
Inner Handle	Case to fix Joint Assembly
Optic	Optical fiber that allows light to pass from the motor's LED light source to the handpiece head
Irrigation Pipe Assembly	Pipes for water supply
Angle Handle A	The case of Middle Bevel Gear, Optic, Irrigation Pipe
Angle Handle Assembly	The case of Joint Gear Assembly, Optic, Head
Component Name	**Function**
Common Components of Handpiece Model CA160 and CA160L	
Spindle Assembly	Receives torque from Middle Gear Assembly and transmits torque to final dental bur
Middle Gear Assembly	Transmitting the rotational force from the Inner Handle Assembly and delivers the rotational force to the Spindle Assembly
Button Assembly	Button for removal and attachment of the hand piece head
Head Cap	Case that wraps the Spindle Assembly. Head Cap is assembled with Button Assembly and Middle Gear Assembly
Head Assembly	The component that is assembled Spindle Assembly, Middle Gear Assembly, Button Assembly, Head Assembly

Gear Box Assembly	It consists of several gears and decelerates.
Joint Gear Assembly	Transmits the torque received from the motor to the Head Assembly
Inner Handle	Case to fix Joint Assembly
Locking Handle	Head assembly's attachment and detachment.
Angle Handle Assembly	The case of Joint Gear Assembly, Optic, Head
Components only Available for Handpiece Model CA160	
Angle Body	The case is installed in Handle Assembly
Components only Available for Handpiece Model CA160L	
Optic	Optical fiber that allows light to pass from the motor's LED light source to the handpiece head
Angle Body	The case is installed in Handle Assembly and protect the optics.

V. INDICATIONS FOR USE/INTENDED USE

Dental Handpiece with models of CA160, CA160L, and CA500L are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, and restorations for polishing teeth.

Dental Handpiece is designed for use by a trained professional in the field of general dentistry.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Fundamental technological characteristics of MICRO-NX Dental Handpiece models CA160, CA160L, and CA500L are substantially equivalent to the predicate device, MICRO-NX Dental Handpiece(K192809) as demonstrated in Table VI-1 below.

Table VI-1. Substantial Equivalence Assessment between MICRO-NX Dental Handpiece and Predicate Device(K192809)

	Proposed Device: Dental Handpiece with models CA160, CA160L, and CA500L	Predicate Device: Dental Handpiece (MICRO-NX, K192809)	Substantial Equivalence Assessments
Intended Use / Indications for Use	Dental Handpiece with models of CA160, CA160L, and CA500L are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, and restorations for polishing teeth. Dental Handpiece is designed for use by a trained professional in the field of general dentistry.	Dental Handpiece with models of SG200, SG200L, SA100L, SA100R, CA100L, and CA100R are intended for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, and restorations for polishing teeth. In addition, Dental Handpiece with models of SG200, SG200L are also intended for	Intended use and indications for use are the same between Dental Handpiece with models of CA160, CA160L, and CA500L and the predicate device Dental Handpiece (MICRO-NX, K192809) for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of fillings, processing and finishing tooth preparations, and restorations for polishing teeth. Dental Handpiece is designed for use by a trained professional in the field of general dentistry.

		implant surgery such as perforating the bone, tapping and threading procedures. Dental Handpiece is designed for use by a trained professional in the field of general dentistry.	Compared to the proposed Dental Handpiece models of CA160, CA160L, and CA500L, the intended use/indications for use of the predicate for SG200 and SG200L model (K192809) have additional intended use/indications for use for implant surgery such as perforating the bone, tapping and threading procedures. This particular, additional indications are not applicable to the proposed Dental Handpiece models of CA160, CA160L, and CA500L. The predicate (K192809) models of SG200 and SG200L are not subject of the substantial equivalence comparison with the proposed Dental Handpiece. Only the predicate models of CA100L and CA100R (K192809), which do not contain the additional intended use/indications for use are subject for substantial equivalence comparison with the proposed Dental Handpiece models CA160, CA160L, and CA500L.
Functional Principle	Dental Handpiece with models of CA160, CA160L, CA500L: Through the micro motor connected to the dental	Through the micro motor connected to the dental treatment unit, the straight and contra-angle handpieces	Similar Functional Principle

	treatment unit, the contra-angle handpieces equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receive the energy, the cooling water and air for treatment and the light for illumination the operating area.	equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receive the energy, the cooling water and air for treatment and the light for illumination the operating area.	
Dimensions	**CA160, CA160L, CA500L** Head size-Length: Up to 15mm Head size-Diameter: Up to 9mm Length: Up to 95mm	Head size-Length: Up to 14mm Head size-Diameter: Up to 9mm Length: Up to 95.80mm	The head size, height, and diameter of Dental Handpiece are broadly in alignment with the dimensions of the predicate, Dental Handpiece (MICRO-NX, K192809). The minute differences in the identified dimensions do not raise different questions in terms of safety and effectiveness.
Direct patient-contacting portions of the device	All materials for Dental Handpiece models are listed in the raw material table above including chemical composition of the waterlines and the patient-contacting portions of the device. Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system - ISO 10993-1:2009)	All materials for Dental Handpiece models are listed in the raw material table above including chemical composition of the waterlines and the patient-contacting portions of the device. Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system - ISO 10993-1:2009)	The proposed Dental Handpiece models CA160, CA160L, and CA500L are additional models to the predicate device of Dental Handpiece (MICRO-NX, K192809) and have identical patient contacting materials to the predicate device. Therefore, predicate device biocompatibility test result per the standards of ISO 10993-1 is applicable to the models of the proposed device.

Indirect patient-contacting portions of the device (water / air lines)	All materials for Dental Handpiece models are listed in the tables above including chemical composition of the waterlines and the patient-contacting portions of the device. Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system - ISO 10993-1:2009)	All materials for Dental Handpiece models are listed in the tables above including chemical composition of the waterlines and the patient-contacting portions of the device. Biocompatible according to ISO 10993-1 (Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management system - ISO 10993-1:2009)	The proposed Dental Handpiece models CA160, CA160L, and CA500L are additional models to the predicate device of Dental Handpiece (MICRO-NX, K192809) and have identical in-direct patient contacting materials to the predicate device. Therefore, predicate device biocompatibility test result per the standards of ISO 10993-1 is applicable to the models of the proposed device.
Chuck Design	Push Button	Push Button, Latch Type	Same, Chuck design of the proposed Dental Handpiece is push button type, whereas the predicate device(K192809) has additional chuck design type of latch type.
Motor Speed Range (RPM's)	Up to 40,000 rpm	Up to 40,000 rpm	Similar Speed Range
Conformance Standards (Handpieces and Motors)	ISO 14457 (Dentistry - Handpieces and motors - ISO 14457:2012)	ISO 14457 (Dentistry - Handpieces and motors - ISO 14457:2012)	Compliant with the same standards for dentistry handpiece and motors.
Conformance Standards (Shanks)	ISO 1797 (2017) "Dentistry - Shanks for rotary and oscillating instruments"	ISO 1797 (2017) "Dentistry - Shanks for rotary and oscillating instruments"	Compliant with the same standards of dentistry shanks.

Conformance Standards (Coupling Dimensions)	ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)	ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)	Compliant with the same standards of ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)
Sterilization	Sterilizable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device - ISO 176651:2006)	Sterilizable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices on the final, finished device - ISO 176651:2006)	Conform to the same standards for user sterilization.
Air / water ports	Internal Spray	Internal/ External Spray	Same, Compared to the predicate device(K192809) which consists of internal and external spray components, the proposed Dental Handpiece only consists of internal spray.
Gear Ratio	CA160, CA160L: 16:1 CA500L: 1:5	20:1/ 1:1	Compared to the predicate device of Dental Handpiece (MICRO-NX, K192809), the addition of a gear ratio of 1:5 and 16:1 does not raise different questions in terms of safety and effectiveness given the favorable test results of performance testing of Dental Handpiece.

Overall, Design verification testing were performed to assess the following critical elements of medical devices used in dentistry applications. The favorable test results of the proposed device which confirmed to meet the FDA recognized standards as well as ISO

standard demonstrate Dental Handpiece retains the substantially equivalent profile in safety and essential performance of medical electrical equipment as the predicate device Dental Handpiece (MICRO-NX, K192809).

- ISO 3964 (2016) "Dental Handpieces – Coupling dimensions" (Recognition List Number: 003 Effective Date: 05/03/1999)
- ISO 14457 (2017) "Dentistry - Handpieces and motors" (Recognition List Number: 031 Effective Date: 09/15/2012)
- ISO 1797 (2017) "Dentistry - Shanks for rotary and oscillating instrument

VII. DESIGN VERIFICATION & PERFORMANCE DATA

The following design verification and performance data are provided in support of the conclusive determination that the proposed dental handpiece is substantially equivalent to the predicate device Dental Handpiece (MICRO-NX, K1192809).

Biocompatibility Testing
The biocompatibility testing conducted for the predicate device Dental Handpiece (K192809) is applicable to the proposed Dental Handpiece models CA160, CA160L, and CA500L. The proposed Dental Handpiece models CA160, CA160L, and CA500L are additional models to the predicate device Dental Handpiece (K192809). All of the patient-contacting raw materials of the proposed Dental Handpiece models are the same as the predicate device Dental Handpiece (K192809) with no new introduction of patient contacting raw materials for the proposed Dental Handpiece models.

In accordance with ISO 10993-1: 2009, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process, the Dental Handpiece models CA160, CA160L, and CA500L is classified as "Externally Communicating Device-Tissue/bone/dentin (Limited contact duration). This is the same classification of the biocompatibility evaluation as the predicate Dental Handpiece (K192809).

The biocompatibility testing of the Dental Handpiece listed below has been conducted in 2019 in order to ensure FDA's latest consensus standards with respect to biocompatibility evaluations are met for the proposed device. The favorable biocompatibility test results drawn in 2019 testing confirms the biocompatibility profile of the Dental Handpiece.

- ISO MEM Elution Using L-929 Mouse Fibroblast Cells (GLP)
- ISO Guinea Pig Maximization Sensitization Test (GLP - 2 Extracts)
- ISO Intracutaneous Irritation Test (GLP - 2 Extracts)
- ISO Materials Mediated Rabbit Pyrogen (GLP)

- ISO Acute Systemic Injection Test (GLP - 2 Extracts)

Design Verification and Validation Testing

The proposed, Micro-NX Dental Handpiece models CA160, CA160L, and CA500L have been evaluated and risk management practice has been implemented in accordance with ISO 14971 Medical devices - applications of risk management to medical devices.

- Appearance Test
- Operation Test
- Rotational Speed Test
- Noise Test
- Spray Test
- Light Test
- Serviceable Year/ Shelf-Life Test

The favorable results of the design verification testing demonstrate the design output of Dental Handpiece conform to the applicable, pre-determined design requirements of the Dental Handpiece. The testing results also further demonstrate the proposed Dental Handpiece models are substantially equivalent to the predicate device (K192809), as the proposed and predicate device are subject to the same applicable test standards of design requirements for dental handpiece.

Therefore, the identified differences in terms of the dimensions and outer appearance between the proposed Dental Handpiece models CA160, CA160L, and CA500L and the predicate (K192809) CA100L and CA100R do not raise different questions in safety and effectiveness compared to the predicate device Dental Handpiece (K192809).

VIII. CONCLUSIONS

Overall, the proposed device is comparable to the predicate device given the fact that its indications for use are the same, and fundamental technological characteristics are equivalent to those of the predicate device Dental Handpiece (MICRO-NX, K192809). The favorable results of the aforementioned design verification and performance testing demonstrate conformance to the appropriate standards pertinent to dental handpieces, and demonstrate that no different questions of safety and effectiveness assessment are being raised compared to the predicate device of Dental Handpiece (MICRO-NX, K192809).