August 25, 2020

Micro-NX Co., Ltd.
% Kyungyoon Kang
CEO
K-Bio Solutions
589 Oakwood Drive
Santa Clara, California 95054

Re: K192809
Trade/Device Name: Dental Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFA
Dated: May 20, 2020
Received: May 27, 2020

Dear Kyungyoon Kang:

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,

For Srinivas “Nandu” Nandkumar, Ph. D.
Director
DHT1B: Division of Dental 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)*
K192809

Device Name
Dental Handpiece

Indications for Use *(Describe)*
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 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.

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

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.

Ⅰ. SUBMITTER

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510(k) Number: K192809
Manufacturer Contact: Sojeong Park (sojeong@micronx.co.kr)
Date Prepared: August 25th, 2020

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: EFA (handpiece, belt and/or gear driven, dental)
- Review Panel: Dental
- Regulatory Class: Class I

Traditional 510(k) Registration (There were no prior submissions for the proposed, Micro-NX Dental Handpiece, which is labeled for 5 year shelf life)

Ⅲ. PREDICATE DEVICES

- SMARTmatic (K163239), Manufacturer: Kaltenbach & Voigt GmbH
- Anthogyr Contra Angles and Handpieces (K093894), Manufacturer: Anthogyr

These predicate devices have not been subject to a design-related recall.

Ⅳ. DEVICE DESCRIPTION

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 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.

The proposed dental handpiece consists of the main body of a handpiece, which is used for transmitting a rotational force for the general dental treatments as well as accessory components, which are used for channeling water and air for further applications to the dental treatments. The torque transmitted from an 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 to be transmitted to the head of the dental handpiece. The rotational force is transmitted under the permitted rotation mechanism.

The product is offered as an electrical-powered Dental Handpiece that is reusable and ergonomically shaped. The dental handpiece can be sterilized by the steam autoclave method. Through the tube and the electrical motor connected to a dental unit, the Dental Handpiece equipped with a handpiece connection according to ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982) receive the energy for the gear, the cooling water and air for cutting treatment. Dental burs and other attachments will be used with the proposed Dental Handpiece per ISO 1797:2017 (Dentistry - Shanks for rotary and oscillating instruments).

Dental Handpiece has been developed with a full range of surgical contra angle intended to be used in implantology. The contra angle-design, size and performance of the proposed Dental Handpiece conform to ISO 14457 (2017) “Dentistry -Handpieces and motors”

The six (6) product codes and models of Dental Handpiece are SG200L, SG200, CA100L, CA100R, SA100L, SA100R.The component names and functional descriptions for critical components of Dental Handpiece are provided in the table below.

Table IV-1. Component Names and Functional Descriptions for Critical Components of Dental Handpiece: SG200L, SG200, CA100L, CA100R

Component Name	Function
Components which are commonly included in the models of SG200L, SG200, CA100L, CA100R	
Spindle Assembly	Receives torque from Middle Gear Assembly and transmits torque to final dental bur

Middle Gear Assembly	Transmitting the rotational force from being Housing Assembly also delivering 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 Middle Gear Assembly and Housing Assembly, and the Button Assembly is assembled
Head Assembly	The component that is assembled Spindle Assembly, Middle Gear Assembly, Button Assembly, Head Assembly
Housing Assembly	Transmits the torque received from Joint Assembly to Middle Gear Assembly
Joint Assembly	Transmits the torque received from the motor to the Housing Assembly
Inner Handle	Case to fix Joint Assembly
Planetary Gear Assembly	The component that is assembled Housing Assembly, Joint Assembly, Inner Handle
Spray Adapter	Adapter to help oil fill the handpiece
Components only available for SG200L	
Optic	Optical fiber that allows light to pass from the motor's LED light source to the handpiece head
Angle Handle	The case of Planetary Gear Assembly, Optic, Head Assembly
Angle Body Assembly	The case is installed in Handle Assembly and has two parts where the light passing through the optical fiber comes out and the part where the Pipe Clip can be fixed
Handle Assembly	The component that is assembled Optic, Angle Handle
Pipe Clip	Clip to fix Outside Pipe mounted on specific groove of Angle Body Assembly
Y-coupling	Supply water from the external water supply line to the spray nozzle and outside pipe
Tube Clip	Fix the external water line to the handpiece

Inside Pipe	Pipes attached to the handpiece head to supply water
Outside Pipe	Pipes fixed to Pipe Clip pipe to supply water
Components only available for SG200	
Angle Handle	The case of Planetary Gear Assembly, Optic, Head Assembly
Angle Body Assembly	The case is installed in Handle Assembly and has two parts where the light passing through the optical fiber comes out and the part where the pipe clip can be fixed
Spray Nozzle	Pipe for water supply mounted on the handpiece head
Pipe Clip	Clip to fix Outside Pipe mounted on specific groove of Angle Body Assembly
Y-coupling	Supply water from the external water supply line to the spray nozzle and outside pipe
Tube Clip	Fix the external water line to the handpiece
Outside Pipe	Pipes fixed to Pipe Clip pipe to supply water
Components only available for CA100L	
Handle Assembly	The component that is assembled Optic, Angle Handle
Angle Body Assembly	The case is installed in Handle Assembly and has two parts where the light passing through the optical fiber comes out and the part where the pipe clip can be fixed
Angle Handle	The case of Planetary Gear Assembly, Optic, Head 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
Components only available for CA100R	

Handle Assembly	The component that is assembled Optic, Angle Handle
Angle Body Assembly	The case is installed in Handle Assembly and has two parts where the light passing through the optical fiber comes out and the part where the pipe clip can be fixed
Angle Handle	The case of Planetary Gear Assembly, Optic, Head Assembly
Irrigation Pipe Assembly	Pipes for water supply

Table IV-2. Component Names and Functional Descriptions for Critical Components of Dental Handpiece: SA100L, SA100R

Components which are commonly included in the models of SA100L, SA100R	
Spindle Assembly	Receives torque from motor and transmits torque to final dental bur
Cam	A Component to fix the bottom of Spindle Assembly
Inner Handle	A component that is assembled Spindle Assembly
Nose Cap	An outer case assembled the front part of Cam Handle Assembly
Cam Handle Assembly	An outer case that is assembled Nose Cap, Angle Handle.
Angle Handle	An outer case assembled the back part of Cam Handle Assembly
Irrigation Pipe Assembly	Pipes for water supply
Handle Fixing Bolt	Assembled and fastened at the bottom of the handpiece
Spray Adapter	Adapter to help oil fill the handpiece
Components only available for SA100L	

Optic	Optical fiber that allows light to pass from the motor's LED light source to the handpiece head

V. INDICATIONS FOR USE/INTENDED USE

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 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Fundamental technological characteristics of MICRO-NX dental handpiece are substantially equivalent to the predicate devices, SMARTmatic and ANTHOGYR Contra angles and Handpieces as demonstrated in Table VI-1 below.

Table VI-1. Substantial Equivalence Assessment between MICRO-NX Dental Handpiece and Predicate Devices

Comparison Category	Proposed Device: Dental Handpiece	Predicate Device: SMARTmatic (K163239)	Predicate Device: ANTHOGYR Contra angles and Handpieces (K093894)	Substantial Equivalence Assessments
Intended Use /Indications for Use	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	The SMARTmatic handpieces 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.	ANTH-OGYR's fully autoclavable contra-angles Implantology Impulsion are devices intended for a wide range of dental procedures including: Implant surgery such as perforating the bone, tapping and threading procedures	Intended use and indications for use are the same between Dental Handpiece and the predicate device of SMARTmatic handpieces, for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, root canal preparations, removal of

	restorations for polishing teeth. In addition, Dental Handpiece with models of SG200, SG200L are also intended for 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.	They are designed for use by a trained professional in the field of general dentistry.		fillings, processing and finishing tooth preparations, and restorations for polishing teeth. The intended use of the predicate, ANTHOGYR for implant surgery such as perforating the bone, tapping and threading procedures is the same as the intended use of Micro-NX dental handpiece for models of SG200, SG200L.
Functional Principle	Through the micro motor connected to the dental treatment unit, the straight and 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.	Through the micro motor connected to the dental treatment unit, the straight and 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.	Through the micro motor connected to the dental treatment unit, the straight and 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.	Same Functional Principle
Dimensions	Head size- Height: Up to 14mm Head size-Diameter: Up to 9mm Length: Up to 95.80mm	Head size-Height: Up to 13.6 mm Head size-Diameter: Up to 9.8 mm Length: Up to 93.4 mm	Head size-Height: Up to 13.02mm Head size-Diameter: Up to 10.07 mm Length: Up to 104.84mm	The head size, height, and diameter of MICRO-NX Dental Handpiece are broadly in alignment with the

				dimensions of the predicate, SMARTmatic handpiece. The minute differences in the identified dimensions do not raise different questions of safety and effectiveness.
Direct patient-contacting portions of the device	All materials for MICRO-NX Dental Handpiece models are listed in the raw material table below 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 the SMARTmatic models are listed in the tables below 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)	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 patient contacting materials of MICRO-NX Handpiece have been tested per the same standards of ISO 10993-1. Given the favorable biocompatibility test results, the differences in patient contacting materials do not raise different questions in terms of safety and effectiveness.
Indirect patient-contacting portions of the device (water / air lines)	All materials for MICRO-NX Dental Handpiece models are listed in the tables below 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 the SMARTmatic models are listed in the tables below 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	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 in-direct patient contacting materials of MICRO-NX Handpiece have been tested per the same standards of ISO 10993-1. Given the favorable biocompatibility test results, the differences in patient contacting materials do not raise different questions of safety and effectiveness.

		system - ISO 10993-1:2009)		
Chuck Design	Push Button, Latch Type	Push Button, Twist-tension Chuck, Snap-on & Screw-in	Push Button, Latch Type	The chuck design of MICRO-NX Dental Handpiece is the same as the predicate, ANTHOGYR (K093894).
Speed Range (RPM's)	Up to 40,000 rpm	Up to 40,000 rpm	Up to 40,000 rpm	Same 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)	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 1797-1 (2011) "Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals"	ISO1797-1(1995) "Dental rotatory instruments - Shanks - Par 1: Shanks made of metal"	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)	ISO 3964 (Dentistry - Coupling dimensions for handpiece connectors - ISO 3964:1982)	Compliant with the same standards of dentistry coupling dimensions.
Sterilization	Sterilisable 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	Sterilisable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a	Sterilisable according to ISO 17665-1 (Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a	Conform to the same standards for user sterilization.

	on the final, finished device - ISO 176651:2006)	sterilization process for medical devices on the final, finished device - ISO 176651:2006)	sterilization process for medical devices on the final, finished device - ISO 176651:2006)	
Air / water ports	Internal/ External Spray	No Spray / External Spray	External Spray	Internal spray function added to provide an additional option to the users. Given the favorable test results of the internal spray components, the addition does not raise different questions of safety and effectiveness.
Gear Ratio	20:1/ 1:1	8:1/32:1/1:1	20:1	Compared to the predicate device of SMARTmatic device, the addition of a gear ratio of 20:1 does not raise different questions of safety and effectiveness given the favorable test results of performance testing of MICRO-NX Dental Handpiece.

Overall, design verification testing was 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 as the predicate devices of SMARTmatic (K163239) and ANTHOGYR Contra angles and Handpieces (K093894).

- 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 instruments"

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 devices of SMARTmatic (K163239), ANTHOGYR Contra angles and Handpieces (K093894).

Biocompatibility Testing
In accordance with ISO 10993-1: 2009, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process, the proposed Dental Handpiece is categorized as a device appropriate for biocompatibility testing required for devices with Tissue/bone/dentin contact with limited <24 hour contact duration. This is the same testing classification of the biocompatibility evaluation as the predicates SMARTmatic(K163239) and ANTHOGYR Contra angles and Handpieces (K093894)

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

Design Verification and Validation testing were performed to verify that the proposed Dental Handpiece meets the pre-determined design requirements and demonstrated design input matched with design outputs. Risk management assessment was conducted and appropriate risk mitigation measures were implemented including verifications of the effectiveness of the implemented risk control measures to mitigate the risks identified within the risk management process (per ISO 14971:2012 Medical Devices - Application of Risk Management to Medical Devices).

- Rotational Speed Testing
- Noise Testing
- Water Supplying Testing
- Light Testing
- Operation Testing
- Appearance Testing

The favorable results of the biocompatibility, design verification performance, and validation testing demonstrate conformance of the proposed Dental Handpiece to the applicable, recognized standards of FDA. The testing results further demonstrate the substantially equivalent profile as

the predicate device, the proposed device are subject to the same applicable test standards under FDA's recognized standards including ISO 10993-1 (2009).

Ⅷ. CONCLUSIONS

Overall, the proposed device is assessed substantially equivalent to the predicate devices given the fact that its indications for use are the same, and fundamental technological characteristics are equivalent to those of the predicates of SMARTmatic (K163239) and ANTHOGYR Contra angles and Handpieces (K093894). The favorable results of the aforementioned design verification and performance testing demonstrate conformance to the appropriate standards pertinent to dental handpieces, and demonstrate substantial equivalence to the identified predicate devices.