November 9, 2023

Micro-NX Co., Ltd.
℅ Brandon Green
RA Associate
K-Bio Solutions
201 South 4th Street, Suite 727
San Jose, California 95112

Re: K232810
Trade/Device Name: Dental Handpiece, Wireless Endodontic Handpiece, endoit
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: September 4, 2023
Received: September 12, 2023

Dear Brandon Green:

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.

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 Adjodha, MChE, RAC, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232810

Device Name
Dental Handpiece, Wireless Endodontic Handpiece, endoit, model no.(EH-C500)

Indications for Use *(Describe)*
The Dental Handpiece, Wireless Endodontic Handpiece, endoit, model no. (EH-C500) is 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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K232810

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, Wireless Endodontic Handpiece, endoit (model number: EH-C500)

I. SUBMITTER

510(k) Correspondent: Brandon Green
RA Associate, K-Bio Solutions (brandon.green@kbiotechsolutions.com)
Tel: 82-2-597-2700

Sponsor: MICRO-NX Co., Ltd.
22, Maeyeo-ro 1 gil, Dong-gu, Daegu
Postal code: 41059, Republic of Korea
Tel: 82-053-650-1000
Fax: 82-053-650-1005

Manufacturer Contact: Haim Yoon (haimyoon1@micronx.co.kr)
Date Prepared: September 4th, 2023

II. SUBMISSION DEVICE

- Trade Name(s) of Device: Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500)
- Regulation Number: 21 CFR 872.4200
- Regulation Name: Dental handpiece and accessories
- Product Code: EKX (Handpiece, Direct Drive, Ac-Powered)
- 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 (K220577) Model CA160, CA160L, and CA500L

III. PREDICATE DEVICES

- Dental Handpiece model CA160L (K220577), Manufacturer: Micro-NX Co., Ltd.
- Endo A Class (K123582), Manufacturer: Saeyang Microtech Co., Ltd.

IV. DEVICE DESCRIPTION

The intended use of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is the same as the intended use of the predicate (K220577) Dental Handpiece model CA160L and similar to the predicate (K123582) Endo A Class.

- Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is 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. The Dental Handpiece is designed for use by a trained professional in the field of general dentistry.

- Predicate Dental Handpiece (K220577) model CA160L is 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. The Dental Handpiece is designed for use by a trained professional in the field of general dentistry.

- Predicate Endo A Class (K123582) has the following intended use: This application area extends to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.

Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) consists of a Main Body, connectable Contra Angle, Charging Cradle, and AC/DC Adapter. The Main Body of the handpiece is used for transmitting rotational force required in general dental treatment. The torque transmitted from a wireless electric micro-motor gets further transmitted to the joint part of the device. 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.

Compared to the predicate device Dental Handpiece model CA160L (K220577), the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) contains additional components of a Charging Cradle and AC/DC Adapter. Therefore, the primary distinction between the predicate device (K220577) and the EH-C500 is their power/charging method. The EH-C500 relies on the AC/DC Adapter and Charging Cradle to recharge its Main Body, whereas the predicate (K220577) receives electrical input from an external electric motor that is typically attached to the distal end of the dental handpiece's Main Body. Thus, the main technological characteristics in terms of achieving the intended use 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 are identical between the predicate (K220577) and Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500)

Compared to the predicate device Endo A Class (K123582), the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) has the same components and similar

technological characteristics including a connectable Contra Angle, charging method, and wireless functionality.

The identified difference between the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) and predicate Dental Handpiece model CA160L (K220577) lies primarily within their power/charging methods. However, this difference has been assessed and it has been determined not to raise different questions regarding the safety or effectiveness of either the predicate devices CA160L and Endo A Class or the proposed device EH-C500, which have been tested according to the FDA's recognized IEC standards listed below:

- IEC 60601-1 (2005) "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- IEC60601-1-2 (2014) "Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests"

The aforementioned IEC testing of the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is provided as eCopy 007 and eCopy 008. Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is provided with a connectable Contra Angle component, that is connected to the Main Body. The Contra Angle and Main Body of the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) together make up the main body system of the device. Essentially, the Contra Angle and Main Body of the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) together serve the similar technological characteristics as the main body system of the predicate (K220577) Dental Handpiece model CA160L. Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is a wireless, electric, and chargeable device utilized in root canal treatment. The battery inside the Main Body of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) generates power to transmit rotational force for the general dental treatments. The speed of the rotation and torque value can be controlled using the buttons on the main body of the device. The rotational force is transmitted under the permitted rotation mechanism.

Components associated with the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) are the Main Body, Contra Angle (EH-A01), Charging Cradle, and AC/DC Adapter. The Charging Cradle and AC/DC Adapter are accessory components of the device.

Components associated with the predicate Dental Handpiece model CA160L are the Main Body handle which includes Contra Angle. The accessory component associated with the CA160L model is the Spray Adapter.

Components associated with the predicate Endo A Class are the Main Body, Contra Angle, Charging Cradle, and AC/DC Adapter. The Charging Cradle and AC/DC Adapter are accessory components of the device.

The components of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) in comparison of those of the predicate devices Dental Handpiece model CA160L and Endo A Class are provided in Table IV-1 below.

Table IV-1 Proposed Device Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) Component Specification

Model	Proposed Device: EH-C500	Predicate Device: CA160L	Predicate Device: Endo A Class
Main Body	**X**	**X**	**X**
Contra Angle	**X**	**X**	**X**
Charging Cradle (accessory)	**X**		**X**
AC/DC Adapter (accessory)	**X**		**X**
Spray Adapter (accessory)		**X**	

The component names and function of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) and predicate Dental Handpiece model CA160L are provided in Table IV-2 and Table IV-3 below.

Table IV-2 Component Names and Functional Descriptions for Critical Components of Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500)

No.	Component Name	Function
A. Components of Main Body of the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500)		
A1	Handpiece Top Case	Top part of the Handpiece case
A2	Handpiece Bottom Case	Bottom part of the Handpiece case
A3	Name plate	Sticker for button identification and exterior design
A4	Button	Button to activate functions of the Dental Handpiece
A5	LCD Plate	Protects LCD
A6	PCB Assembly	Internal PCB
A7	Handle Cap	For connecting internal parts
A8	Index Ring	For connecting internal parts
A9	Motor Assembly	Motor that transmits rotational power
A10	Battery	Power the motor
B. Contra Angle (EH-A01)		
B1	Head Assembly	Transmits rotational power from the handpiece to the bur
B2	Shank Assembly	Connects Handpiece and the Head part

Table IV-3 Component Names and Functional Descriptions for Critical Components of Dental Handpiece model CA160L

No.	Component Name	Function
A. Components of Main Body of the Dental Handpiece Model CA160L		
A1	Spindle Assembly	Receives torque from Middle Gear Assembly and transmits torque to final dental bur
A2	Middle Gear Assembly	Transmitting the rotational force from the Inner Handle Assembly and delivers the rotational force to the Spindle Assembly
A3	Button Assembly	Button for removal and attachment of the hand piece head
A4	Head Cap	Case that wraps the Spindle Assembly. Head Cap is assembled with Button Assembly and Middle Gear Assembly
A5	Head Assembly	The component that is assembled Spindle Assembly, Middle Gear Assembly, Button Assembly, Head Assembly
A6	Gear Box Assembly	It consists of several gears and decelerates.
A7	Joint Gear Assembly	Transmits the torque received from the motor to the Head Assembly
A8	Inner Handle	Case to fix Joint Assembly
A9	Locking Handle	Head assembly's attachment and detachment.
A10	Angle Handle Assembly	The case of Joint Gear Assembly, Optic, Head
B. Components only available for CA160L		
B1	Optic	Optical fiber that allows light to pass from the motor's LED light source to the handpiece head
B2	Angle Body	The case is installed in Handle Assembly and protect the optics.

V. INDICATIONS FOR USE/INTENDED USE

Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Fundamental technological characteristics of Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) are substantially equivalent to the predicate devices, MICRO-NX Dental Handpiece model CA160L (K220577) and Saeyang Microtech Co., Ltd. Endo A Class (K123582) as demonstrated in Table VI-1 below.

Table VI-1. Substantial Equivalence Assessment between Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) and Predicate Devices (K220577) and K(123582)

	Proposed Device: Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500)	Predicate Device: Dental Handpiece model CA160L (MICRO-NX, K220577)	Predicate Device: Endo A Class (Saeyang Microtech Co., Ltd., K123582)	Substantial Equivalence Assessments
Intended Use / Indications for Use	Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is 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 model CA160L is 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.	This application area extends to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.	Intended use and indications for use are the same between Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) and the predicate device Dental Handpiece model CA160L 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.
Functional Principle	Compared to the predicate (K220577) Dental Handpiece model CA160L that is coupled to handpiece connectors to receive energy, the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) has a built-in battery in the main body that generates torque force to transmit rotational force to the contra angle for the general dental treatments.	Through the micro motor connected to the dental treatment unit, the Dental Handpiece model CA160L contra angle handpiece is equipped with a handpiece connection that receives the energy, the cooling water and air for treatment and the light for illumination the operating area.	The motor turned by the power converted into DC2.4V by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated, stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller.	Similar Functional Principle In order to address the wireless function of the proposed device, an additional predicate device, Endo A Class, is being submitted. The wireless function does not raise questions about the safety or effectiveness of the proposed device compared to the predicate device.
Dimensions	**Main Body** Width: 23mm Length: 27mm Height: 155mm **Contra Angle (EH-A01)** Diameter: 17mm Length: 71mm Height: 30mm Head Length: 8.1mm	Connection Diameter: 20mm Length: 95mm Head Length: 14mm Head Diameter: 9mm	**Main Body** Width: 27mm Length: 28mm Height: 192mm	The head size, height, and diameter of Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) are broadly in alignment with the dimensions of the predicate

	Head Diameter: 10.7mm			(K220577) Dental Handpiece model CA160L. The minor differences in the identified dimensions do not raise different questions in terms of the safety or effectiveness of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500).
Direct patient-contacting portions of the device	All materials for the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) are listed in the raw material table 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 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)	The proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is an additional model to the predicate (K220577) Dental Handpiece model CA160L and has identical in-direct patient contacting materials. Therefore, the predicate device biocompatibility test results per the standard of ISO 10993-1 are applicable to the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500).
Indirect patient-contacting portions of the device	All materials for the Dental Handpiece, Wireless Endodontic	All materials for Dental Handpiece model CA160L are listed in the tables above including	Biocompatible according to ISO 10993-1 (Biological evaluation of	The proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit

(water / air lines)	Handpiece, endoit (model number: EH-C500) are listed 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)	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)	medical devices - Part 1: Evaluation and testing within a risk management system - ISO 10993-1:2009)	(model number: EH-C500) is an additional model to the predicate (K220577) Dental Handpiece model CA160L and has identical in-direct patient contacting materials. Therefore, the predicate device biocompatibility test results per the standard of ISO 10993-1 are applicable to the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500).
Charging Method	Charging Cradle	External electric motor	Charging Cradle	The charging method of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is a charging cradle, identical to the predicate device (K123582).
Chuck Design	Push Button Chuck	Push Button Chuck	Push Button Chuck	The chuck design of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is push button chuck, identical to the predicate device (K220577).

Motor Speed Range (RPM's)	120 ~ 500 rpm	Up to 20,000 rpm	140-500rpm	The motor speed range of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is within a lower range compared to the predicate (K220577) CA160L Dental Handpiece model. Since the maximum speed range of the predicate device encompasses the speed range of the proposed model, it does not have any significant impact on establishing substantial equivalence.
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 (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.
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,	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,	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,	Conform to the same standards for user sterilization.

	finished device - ISO 176651:2006)	finished device - ISO 176651:2006)	finished device - ISO 176651:2006)	
Gear Ratio	1:1	16:1	4:1, 10:1, 16:1, 20:1	Compared to the predicate (K220577) of Dental Handpiece model CA160L gear ratio of 16:1, the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) lower gear ratio of 1:1 does not raise different questions in terms of the safety or effectiveness of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500).

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 that the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) retains the substantially equivalent profile in safety and essential performance of medical electrical equipment as the predicate (K220577) Dental Handpiece model CA160L and predicated (K123582) Endo A Class.

- 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

The following IEC standard tests have been completed to evaluate electrical safety and performance of the Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500):

- IEC 60601-1 (2005) "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"

- IEC60601-1-2 (2014) “Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests”

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 model CA160L (MICRO-NX, K220577).

Biocompatibility Testing
The biocompatibility testing conducted for the predicate device Dental Handpiece model CA 160L(MICRO-NX, K220577) is applicable to the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500). The proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is an additional model to the predicate device Dental Handpiece model CA160L (MICRO-NX, K220577). All of the patient-contacting raw materials of the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) are the same as the predicate device Dental Handpiece (MICRO-NX, K220577) with no new introduction of patient contacting raw materials for the proposed Dental Handpiece model.

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, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is categorized under “Externally Communicating Device-Tissue/bone/dentin (Limited contact duration). This is the same category of the biocompatibility evaluation as the predicate (K220577) Dental Handpiece model CA160L.

The biocompatibility testing has been conducted with the FDA-approved Dental Handpiece model SG200L (K192809) in 2019 in order to ensure FDA’s latest consensus standards with respect to biological safety evaluations are met for the proposed device. The predicate (K220577) Dental Handpiece model CA160L was approved by the FDA on July 29th, 2022 and in this submission the Dental Handpiece including model SG200L was used as the predicate device (K192809) for substantial equivalence. The Dental Handpiece model CA160L (K220577) and Dental Handpiece including model SG200L (K192809) were assessed as substantially equivalent and the biocompatibility test results of the Dental Handpiece model SG200L was used as evidence for the Dental Handpiece CA160L (K220577).

- 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, Wireless Endodontic Handpiece, endoit (model number: EH-C500) has been evaluated and risk management practices have been implemented in accordance with ISO 14971:2019/A1:2021 **Medical devices - applications of risk management to medical devices.**

- Appearance Test
- Operation Test
- Rotational Speed Test
- Noise Test
- Serviceable Year/ Shelf-Life Test
- IEC 60601-1
- IEC 60601-1-2

The favorable results of the design verification testing demonstrate the design output of Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) conforms to the applicable, pre-determined design requirements of the Dental Handpiece. The testing results also further demonstrate the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) is substantially equivalent to the predicate (K220577) Dental Handpiece model CA160L, as the proposed and predicate device are subject to the same applicable test standards of design requirements for dental handpieces.

Therefore, the identified differences in terms of the dimensions and outer appearance between the proposed Dental Handpiece, Wireless Endodontic Handpiece, endoit (model number: EH-C500) and the predicate (K220577) Dental Handpiece model CA160L do not raise different questions regarding the safety or effectiveness of the proposed device.

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 predicate device Dental Handpiece (MICRO-NX, K220577). The positive outcomes from the design verification and performance testing mentioned above confirm alignment with the relevant standards related to dental handpieces. Furthermore, they highlight that there are no additional concerns regarding safety and effectiveness assessment when compared to the predicate devices of Dental Handpiece model CA160L (MICRO-NX, K220577) or the Endo A Class (K123582).