May 9, 2022

CEFLA S.C.
Lorenzo Bortolotti
Regulatory Affairs
Via Selice Provinciale 23/A
Imola, BO 40026
ITALY

Re: K213022
Trade/Device Name: CEFLA Dental Micromotors: i-MMr, i-MMr L, i-MMs, i-XR3, i-XR3 L, i-XS4, handy POWER, handy POWER LED, implantor LED
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: April 8, 2022
Received: April 11, 2022

Dear Lorenzo Bortolotti:

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)*
K213022

Device Name
CEFLA Dental Micromotors: i-MMr , i-MMr L , i-MMs ; i-XR3 , i-XR3 L , i-XS4 ; handy POWER , handy POWER LED , implantor LED .

Indications for Use *(Describe)*
The CEFLA Dental Micromotors are brushless electric micromotors controlled by a control unit inside CEFLA Dental Units.
They are intended to be connected with an ISO-type handpiece attachment: straight or contra-angle of equal, gear reducing, or gear increasing speed.
They are intended for professional use in dental surgery such as: preventive dentistry, restorative applications, endodontic treatment, prosthetic applications and implantology practices.

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, AS REQUIRED BY CFR 807.92

K213022

Submitter's Name:	CEFLA S.C.
Address:	Via Selice Provinciale 23/a Imola, BO 40026 ITALY Tel. +39 0542 653111 Fax +39 0542 653444
Establishment Registration Number:	3006610845
Summary Preparation Date:	May 4th,2022
Contact Person:	Lorenzo Bortolotti, Regulatory Affairs
Telephone Number:	+39 0542 653441
Email:	regulatory@cefla.it

Trade/Device name:	CEFLA Dental Micromotors: i-MMr , i-MMr L , i-MMs ; i-XR3 , i-XR3 L , i-XS4 ; handy POWER , handy POWER LED , implantor LED
Common or Usual Name:	Dental brushless electric handpiece micromotor
Classification Name:	Dental Handpiece and Accessories Classification Name: Dental handpiece and accessories. Device Class: I Product Code: EBW Regulation Number: 21 CFR §872.4200
Description:	The CEFLA Dental Micromotors are brushless electric micromotors controlled by a control unit inside CEFLA Dental Units. The dental electric micro-motor is a dental tool, which allows performing the rotation, at a variable speed, of a drill (or another tool) supported by a handpiece connected to the micromotor. It is used for dental procedures concerning restorative and prosthetic dentistry, implant surgery, endodontic (including the reciprocating function). This device is included in the Instrument Boards of the Dental Units. The CEFLA Dental Micromotors family presents two versions:

	1) long version (long) with Led light, especially suitable for implant & endodontic procedures; 2) short version (short) with optional Led light, especially suitable for prosthetic & restorative procedures. Both versions are manufactured with the same essential technical specifications and mechanical performances; the only difference is related to the different lengths and the maximum available torques. Furthermore, both versions of micro-motors are intended to be connect with the following two parts: 1) CEFLA Dental Unit, legally marketed in USA, thought a cord for connection between micromotor and the dental unit system including electronic board; 2) handpieces which transmit movement to their tips or other instrument, legally marketed in USA.
Indication for Use:	The CEFLA Dental Micromotors are brushless electric micromotors controlled by a control unit inside CEFLA Dental Units. They are intended to be connected with an ISO-type handpiece attachment: straight or contra-angle of equal, gear reducing, or gear increasing speed. They are intended for professional use in dental surgery such as: preventive dentistry, restorative applications, endodontic treatment, prosthetic applications and implantology practices.
Identification of Predicate Device:	CEFLA S.C. will refer to the following predicate device (1): Proprietary Name: W&H Classification Name: Dental Handpiece and Accessories, 21 CFR 872.4200 Registered Establishment Name: 9681479 W&H Dentalwerk Buermoos GmbH Ignaz-Glaser-Strasse 53 Burmoos, AT 5111 Owner/Operator: W&H Establishment Operations: Manufacturer 510 (k): K181858 Device Name: Electric Handpiece Motor EM-12 L Applicant: W&H CEFLA S.C. will refer to the following reference device (2): Proprietary Name: NAKANISHI INC. Classification Name: Dental handpiece and accessories, 21 CFR 872.4200 Registered Establishment Name: NAKANISHI INC. 700 Shimohinata Kanuma-Shi, Tochigi-Ken Japan 322-8666 Owner/Operator: NAKANISHI INC.

Establishment Operations: Manufacturer
510 (k): K173905
Trade Name: Surgic Pro+ / Surgic Pro
Common Name: Controller, Foot, Handpiece And Cord
Handpiece, Rotary Bone Cutting
Handpiece, Contra- And Right-Angle Attachment, Dental
Applicant: NAKANISHI INC.

CEFLA S.C. will refer to the following reference device (3):

Proprietary Name: A-dec
Classification Name: Controller, Foot, Handpiece and Cord, 21 CFR 872.4200
Registered Establishment Name:
A-dec, Inc.
2601 Crestview Drive
Newberg, OR 97132
Owner/Operator: A-dec
Establishment Operations: Manufacturer
510 (k): K133776
Trade Name: A-declW&H Electric Motor, Model EA-53
Common Name: Dental Handpiece Electric Motor
Applicant: A-dec

CEFLA S.C. will refer to the following reference device (4):

Proprietary Name: DENTSPLY International
Classification Name: Dental Handpiece and Accessories, 21 CFR 872.4200
Registered Establishment Name:
DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Swreet
York, PA 17405
Owner/Operator: DENTSPLY International
Establishment Operations: Manufacturer
510 (k): K103653

Trade Name: E3 TORQUE CONTROL MOTOR
Common Name: dental motor
Applicant: DENTSPLY International

Comparison of technological characteristics with the predicate and reference devices:		**Subject Device**	**Predicate Device (1)**	**Reference Device (2)**	**Reference Device (3)**	**Reference Device (4)**	**Justifications for differences**
			K181858	K173905	K133776	K103653	
	Trade/ Device Name	CEFLA Dental Micromotors	Electric Handpiece Motor EM-12 L	Surgic Pro, Surgic Pro+	A-dec EA-53	e3™Torque Control Motor	
	Applicant	CEFLA S.C	W&H	Nakanishi, Inc	A-dec	Dentsply International	
							//
	Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	No difference
	Regulatory Class	Class I	Class I	Class I	Class I	Class I	No difference
	Product Code	EBW	EBW	EBW	EBW	EBW	No difference
	Indications for Use	The CEFLA Dental Micromotors are brushless electric micromotors controlled by a control unit inside CEFLA Dental Units. They are intended to be connected with an ISO-type handpiece attachment: straight or contra-angle of equal, gear reducing, or gear increasing speed. They are intended for professional use in dental surgery such as: preventive dentistry, restorative	Electric Handpiece Motor EM-12 L is a brushless DC electric micromotor controlled by a control unit. The electrical drive, EM-12 L is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and	The Surgic Pro+ / Surgic Pro is intended for use in dental oral surgery and dental implant. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard	The A-declW&H Electric Motor kit is a device system comprised of a control unit that drives a DC electric micromotor that is activated by means of a footswitch. It is intended for use in general dental applications such	The e3 Torque Control Motor is a medical device designed for use by dentists for use with dental root canal instruments in continuous rotation with torque control or in reciprocating movement.	Similar Indication for use with the predicate device, which includes 4 out of 5 total dental applications (preventive dentistry, restorative applications, endodontic therapy, prosthodontics applications); implantology application of the subject device is similar to reference device 2.

	applications, endodontic treatment, prosthetic applications and implantology practices.		endodontic therapy, prosthodontics applications such as crown preparations.	tissues in the mouth.	as: cutting a tooth for cavity preparation, crown preparation, crown finishing, inlay, filing, polishing, prophylaxis and endodontic treatment, with use of a straight, right-angle or contra-angle ISO E-type handpiece attachment of equal speed, gear-reduction speed, or gear-increasing speed.		
Main Dental Applications	Implantology Prosthetic Endodontic Restorative	Prosthetic Restorative	Preventive dentistry, restorative applications, endodontic therapy, prosthodontics applications	Implantology Oral Surgery	Prosthetic Endodontic Restorative	Endodontic	No difference. All dental application are covered by predicate and reference devices.
Device Type	Sub-assembly device intended to be incorporated into a dental unit		Sub-assembly device intended to be incorporated into a dental unit	Stand-alone device	Sub-assembly device intended to be incorporated into a dental unit	Stand-alone device	No difference. The proposed dental Micromotors are equivalent to their predicate devices
Technological Characteristics **(mechanism of action)**	Electric brushless micromotor driving dental handpieces fitted with appropriate tools. The micromotor movement, speed and torque are controlled by a dentist through a software-based drive unit.		Electric brushless micromotor driving dental handpieces fitted with appropriate tools. The micromotor movement, speed and torque are controlled by a dentist through a	Electric brushless micromotor driving dental handpieces fitted with appropriate tools. The micromotor movement, speed and torque are controlled by a	Electric brushless micromotor driving dental handpieces fitted with appropriate tools. The micromotor movement, speed and torque are	Electric brushless micromotor driving dental handpieces fitted with appropriate tools. The micromotor movement, speed and torque are	No difference. The proposed dental Micromotors are equivalent to their predicate devices

			software-based drive unit.	dentist through a software-based drive unit.	controlled by a dentist through a software-based drive unit.	controlled by a dentist through a software-based drive unit.	
Micromotor Length	47.5 mm	35 mm	31.55 mm	103.3 mm (with cord connection)	36.7 mm	-	No significant difference. The length derived from stator and rotor dimensions. The micro motors with higher torque are longer. Proposed devices are inside the predicate and references device length range.
Micromotor Diameter	22 mm	22 mm	22 mm	23.5mm	-	-	Not significant differences. The external diameter is basically a consequence of ISO-type connection to handpiece.
Handpiece coupling:	ISO 3964		ISO 3964	ISO 3964	ISO 3964	-	No difference
Range of rotation speed	100 – 40,000 rpm		100 – 40,000 rpm	200 – 40,000 rpm	100 – 40,000 rpm	250 – 1000 rpm (at the contra-angle)	No significant difference. The operative Torque and Rotation speed for the proposed "CEFLA Dental Micromotors", as well as the predicate device and the reference devices, are adjustable by the doctor on dental units or control units depending on the

Maximum torque	5.3 Ncm	3.3 Ncm	3 Ncm	5 Ncm	3 Ncm	20-410 gram-cm	specific applications and the connected handpiece and tip. The proposed device rotation speed and torque ranges includes or are identical to those of the predicate and reference devices declared values. There isn't change in their functionality.
Cooling type	Air		Air	Air	Air	Air	No difference
Direction of rotation	Forward/Reverse operation.		Forward/Reverse operation.	Forward/Reverse operation.	Forward/Reverse operation.	Forward/Reverse operation.	No difference
Operating mode:	Rotary and Reciprocating movement.	Rotary	Rotary	Rotary	Rotary	Rotary and Reciprocating movement.	The subjected devices allow to perform both Rotary and Reciprocating movement. Reciprocating movement is a function especially suitable for endodontic application, like for K103653 reference device (4).
Light:	Whit Led	Two variants: with Led & without Led incorporated	With Led	Two variants: with Led & without Led incorporated.	With Led	-	No significant difference. It's just a marketing choice to make a version without Light available for short micromotor.
Water Pressure	2.5 ± 0,2 bar		0.5 to 3 bar	-	-	-	No significant difference. The water pressure is between the predicate and reference devices declared values and it's in accordance with standard UNI EN ISO

						14457 par 5.6.3 Water supply that indicates 250kPa (2,5 bar).
Air Pressure	3 ± 0,2 bar	3 ± 0,3 bar (range 0.5 to 3 bar)	-	-	-	No difference
Contact Materials	Indirect contact with: Stainless Steel. Materials and surface in compliance with ISO 10993-1 and ISO 14457.	Materials and surface in compliance with ISO 10993-1 and ISO 14457.	Materials and surface in compliance with ISO 10993-1 and ISO 14457.	Stainless Steel. Materials and surface in compliance with ISO 10993-1 and ISO 14457.	Materials and surface in compliance with ISO 10993-1.	No significant differences. Materials and Surface are in compliance with the same biocompatibility and safety requirements of applicable standard ISO 10993-1 and ISO 14457.
Working times	Intermittent operation.	Intermittent operation.	Intermittent operation.	Intermittent operation.	-	No difference
Micromotor Sterilization:	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	-	No difference
Electrical safety:	Complies with IEC 60601-1.	Complies with IEC 60601-1.	Complies with IEC 60601-1.	Complies with IEC 60601-1.	Complies with IEC 60601-1.	No difference
Electromagnetic compatibility:	Complies IEC 60601-1-2.	Complies IEC 60601-1-2.	Complies IEC 60601-1-2.	Complies IEC 60601-1-2.	Complies IEC 60601-1-2.	No difference

Non-clinical Performance Testing:

Electrical safety Test was conducted and performed in accordance with IEC 60601-1.
Electromagnetic compatibility Test was conducted and performed in accordance with IEC 60601-1-2.
Usability test was conducted in accordance to IEC 60601-1-2.
Application of usability engineering was conducted in accordance to IEC 62366.
Mechanical Performance and cooling flows and Visual inspection were conducted in accordance to ISO 14457.
Evaluation of biocompatibility is based on:
ISO 10993-1 “Biological evaluation of medical devices - Part 1: Evaluation and Testing”;
ISO 10993-5 “Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity”.
Validation of the reprocessing according “FDA guidance Reprocessing Medical Devices Health Care Settings: Validation Methods and Labeling. “
Evaluation of sterility test after reprocessing is based on ISO 11737-2.

Clinical Testing: Clinical performance testing was not conducted.

Conclusion:	CEFLA S.C. considers the CEFLA Dental Micromotors to be substantially equivalent to the predicate device and references devices listed above. This conclusion is based on the similarities in intended use, principle of operation, functional design, and established medical use. Differences between the devices shown in the comparison section above are minor and do not have any negative effect on substantial equivalence.