April 1, 2024

CEFLA S.C.
Simona Daidone
Regulatory Affairs
Via Selice Provinciale N.23/A
Imola, Bologna 40026
ITALY

Re: K230895
Trade/Device Name: CEFLA Dental Micromotors: i-MMr, i-MMr L, i-MMr L FLUO, i-MMs, i-MMs FLUO; i-XR3, i-XR3 L, i-XR3 L FLUO, i-XS4, i-XS4 FLUO; handy POWER, handy POWER LED, handy POWER LED FLUO, implantor LED, implantor LED FLUO
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: March 5, 2024
Received: March 5, 2024

Dear Simona Daidone:

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 E. 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)*
K230895

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

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 – K230895

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:	March 28th,2024
Contact Person:	Simona Daidone, Regulatory Affairs
Telephone Number:	+39 0542 653441
Email:	regulatory@cefla.it
Trade/Device name:	CEFLA Dental Micromotors: i-MMr, i-MMr L, i-MMr L FLUO, i-MMs, i-MMs FLUO; i-XR3, i-XR3 L, i-XR3 L FLUO, i-XS4, i-XS4 FLUO; handy POWER, handy POWER LED, handy POWER LED FLUO, implantor LED, implantor LED FLUO
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) available in two variants: with white Led light, or with white and UV LED light; the long version is especially suitable for implant & endodontic procedures;

	2) short version (short) available in three variants: without any incorporated LED, with optional white Led light, or with white and UV LEDs; the short version is 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, through 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. The near-UV LED light is limited to visualization of dental composites with limited exposure time (i.e., observation of the margin of the composite and tooth structure). The near-UV LED light is not intended for use during rotation of the handpiece.
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 devices:

Predicate device:

Proprietary Name: CEFLA
Classification Name: Dental Handpiece and Accessories, 21 CFR 872.4200
Registered Establishment Name: 3006610845
CEFLA S.C.
Via Selice Provinciale 23/a
Imola, BO 40026 ITALY
Owner/Operator: CEFLA
Establishment Operations: Manufacturer
510 (k): 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
Applicant: CEFLA

Reference device:

Device name: VALO Grand Corded and accessory Lenses
510(k) number: K210550
Device Classification Name: Ultraviolet activator for polymerization
Regulation number: 21 CFR 872.6070
Device Class: Class II
Product Code: EBZ
Secondary Product Code: EAQ, PEQ

Applicant: Ultradent Product, Inc. 505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Reference Device:

Device name: VALO X, VALO X accessory Lenses
510(k) number: K220471
Device Classification Name: Ultraviolet activator for polymerization
Regulation number: 21 CFR 872.6070
Device Class: Class II
Product Code: EBZ
Secondary Product Code: EAQ, PEQ
Applicant: Ultradent Product, Inc. 505 West Ultradent Drive (10200 South)
South Jordan, UT 84095

Comparison of technological characteristics with the predicate and reference devices:

	Subject Device	**Predicate Device**	**Reference device**	**Reference device**	**Justifications for differences**
	K230895	**K213022**	**K210550**	**K220471**	
Trade/ Device Name	CEFLA Dental Micromotors: i-MMr, i-MMr L, i-MMr L FLUO, i-MMs, i-MMs FLUO; i-XR3, i-XR3 L, i-XR3 L FLUO, i-XS4, i-XS4 FLUO; handy POWER, handy POWER LED, handy POWER LED FLUO, implantor LED, implantor LED FLUO	CEFLA Dental Micromotors: i-MMr, i-MMr L, i-MMs; i-XR3, i-XR3 L, i-XS4; handy POWER, handy POWER LED, implantor LED	Valo^{tm} Grand Corded and Accessory Lenses	VALO X; VALO X Accessory Lenses	
Applicant	CEFLA S.C	CEFLA S.C	Ultradent Products, Inc.	Ultradent Products, Inc.	
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.6070	21 CFR 872.6070	No difference with the predicate device

	Regulatory Class	Class I	Class I	Class II	Class II	No difference with the predicate device

	Product Code	EBW	EBW	EBZ, EAQ, PEQ	EBZ, EAQ, PEQ	No difference with the predicate device
	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 applications, endodontic treatment, prosthetic applications and implantology practices.	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.	VALO Grand Corded: Source of illumination for curing photo-activated dental restorative materials and adhesives. VALO Accessory Lenses: The VALO Accessory Lenses are multiple-use accessory lenses intended to provide illumination to aid in visualization during oral procedures and augment the VALO family of curing lights, which are a source of illumination for curing photo-activated dental restorative materials and adhesives. VALO Accessory Lenses are not intended for complete cure of phot-activated materials and adhesives.	VALO X curing light is a source of illumination for curing photo-activated dental restorative materials and adhesives. It is also intended to provide illumination to aid in visualization during oral procedures. VALO X curing light accessory/ diffusor lenses are not intended for complete cure of photo-activated materials and adhesives.	No difference with the predicate device. The intended use of the reference devices are different from the intended use of the proposed micromotors because they are a different device. The comparison only refers to the near-UV LED light present in the proposed device, in the reference devices. The intended use of the near-UV LED of the proposed device is to illuminate the oral cavity in the area to be treated, as with the white LED.

						Therefore, the intended use of the near-UV LED is similar to the intended use of the reference devices and of the lenses of the reference devices.
Main Dental Applications	Implantology Prosthetic Endodontic Restorative Prosthetic Restorative		Implantology Prosthetic Endodontic Restorative Prosthetic Restorative		Restorative	Restorative	No difference
Device Type	Sub-assembly device intended to be incorporated into a dental unit		Sub-assembly device intended to be incorporated into a dental unit		Curing light	Curing light	No difference with the predicate device
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 software-based drive unit.		With its broadband spectrum, VALO Grand Corded is designed to polymerize all light cured products in the wavelength range of 385-515nm per ISO 10650. VALO has a medical grade, international power supply and is suitable for power outlets from 100 to 240 volts. The handpiece is designed to rest in a standard dental unit bracket or can be custom mounted using the bracket included with the kit.	With its broadband spectrum, VALO™ X curing light is designed to polymerize all light-cured products in the wavelength range of 380–515 nm per ISO 10650:2018. The VALO X curing light can be used in a corded or cordless	No difference with the predicate device.
						configuration	

							using the Ultradent VALO rechargeable batteries or provided VALO X cord adapter. The curing light is designed to rest in a standard dental unit bracket or can be custom-mounted using the VALO surface mounting bracket included with the kit.	
	Micromotor Length	47.5 mm	35 mm	47.5 mm	35 mm	NA	NA	No difference
	Micromotor Diameter	22 mm	22 mm	22 mm	22 mm	NA	NA	No difference
	Handpiece coupling:	ISO 3964		ISO 3964		NA	NA	No difference

Range of rotation speed	100 – 40,000 rpm		100 – 40,000 rpm		NA	NA	No difference
Maximum torque	5.3 Ncm	3.3 Ncm	5.3 Ncm	3.3 Ncm	NA	NA	No difference
Cooling type	Air		Air		NA	NA	No difference
Direction of rotation	Forward/Reverse operation.		Forward/Reverse operation.		NA	NA	No difference
Operating mode:	Rotary and Reciprocating movement.	Rotary	Rotary and Reciprocating movement	Rotary	Standard Power Mode: 1000 mW/cm^2 High Power Plus Mode: 1600mW/cm^2 Xtra Power Mode: 3200mW/cm^2	Standard Power Mode: 1,100 mW/cm^2 Xtra Power Mode: 2,200mW/cm^2	No difference with the predicate device
Light:	Two variants: with & without near UV LED incorporated, white LED is always incorporated	Three variants: 1. without any LED incorporated;	White Led	Two variants: with white Led & without white Led incorporated	LED light, blue and violet wavelengths 12mm head size	LED light, blue and violet wavelengths (Curing mode)	No significant difference. The micromotors are available in more versions to include a UV led in addition to the white led already present

			2. with white LED incorporated; 3. with White and near UV LEDs incorporated				LED light, violet or white wavelengths (Diagnostic mode) 12.5mm head size	in order to provide visibility of materials and parts of the patient's mouth to facilitate dental practice in particular in restorative modalities. The features of the LED are also similar to those of the reference devices.
	Maximum Radiance	11800 W/(m^2*sr)		NA		-	-	

	Maximum Irradiance	0,034 mW/cm^2 Note: this value has been measured according to test procedure of IEC 62471.	NA	Standard: 900 mW/cm^2 High: 1,500 mW/cm^2 Xtra: 2,100mW/cm^2	Standard Power Mode: 1,100 mW/cm^2 Xtra Power Mode: 2,200 mW/cm^2 Black light: 425 mW/cm^2	In comparison to the reference devices, the light intensity of the LEDs of the proposed device are lower than the one of the reference devices,

						because the proposed device does not have the function of polymerization but it is only intended to illuminate the oral cavity in restorative procedure, in order to distinguish composite materials.
	Maximum Electrical Power Consumption	450 mW	650 mW	-	Black light mode: 522 mW	In comparison to the reference devices, , the light intensity of the LEDs of the proposed device are lower than the one of the Reference devices , because the proposed device does not have the function of polymerization but it is only

						intended to
						illuminate the oral cavity in restorative procedure, in order to distinguish composite materials.
	Exposure time for each cycle	300 seconds (maximum value)	NA	Standard: 10 seconds Xtra: 5 seconds These are the usual exposure time for curing programs.	Black light mode: 60 seconds	In comparison to the Reference devices, the maximum continuous exposure time appears higher but the light intensity of the LEDs of the proposed device are lower than the reference devices.
	Peak wavelength	395 nm ± 5 nm	395 nm ± 5 nm	VALO Grand Corded: Nominal values: 395-415nm and 440-480nm Accessory Lenses: All lenses match the curing lights peak wavelengths except: ≤420 nm wavelength (Black Light Lens),	VALO X: Nominal values: 380-420nm and 420-515nm VALO X Accessory Lenses:	No difference with the predicate device. The proposed device does not reach wavelengths in

				500-570nm peak wavelengths (TransLume Green Lens)	All lenses match the curing lights peak wavelengths except: ≤420 nm wavelength (Diffuser Lens in Black Light Diagnostic Mode) ≥500 nm peak wavelength (Translume Lens, any mode)	the range of 440 – 480 nm like the reference devices, because the polymerization function is not possible with the proposed device. The peak wavelength of the proposed device is similar to the peak wavelength of the black light lens in diagnostic mode (≤420 nm) of the reference device.
	Water Pressure	2.5 ± 0,2 bar	2.5 ± 0,2 bar	NA	NA	No difference
	Air Pressure	3 ± 0,2 bar	3 ± 0,2 bar	NA	NA	No difference
	Contact Materials	Indirect contact with: Stainless Steel. Materials and surface in compliance with ISO 10993-1 and ISO 14457.	Indirect contact with: Stainless Steel. Materials and surface in compliance with ISO 10993-1 and ISO 14457.	NA	NA	No difference
	Working times	Intermittent operation.	Intermittent operation.	NA	NA	No difference
	Micromotor Sterilization:	Sterilized by user (steam sterilization)	Sterilized by user (steam sterilization)	NA	NA	No difference
	Electrical safety and Electromagnetic Compatibility:	Complies with IEC 60601-1 and IEC 60601-1-2.	Complies with IEC 60601-1 and IEC 60601-1-2.	NA	NA	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 Photobiological safety test was conducted and performed in accordance with IEC 62471. All other non-clinical performance testing were not repeated because the tests performed for the predicate device K213022 can be considered valid also for the proposed variants of device.
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. 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.