April 11, 2025

Foshan COXO Medical Instrument Co., Ltd.
Zhaorong Li
Certification Manager
No.17, Guangming Ave, New Light Source Industrial Base,
Nanha National High-tech Zone
Foshan, Guangdong 528226
China

Re: K243921
Trade/Device Name: LED Curing Lights (DB686 HALO)
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ, EAQ
Dated: February 25, 2025
Received: February 25, 2025

Dear Zhaorong Li:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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)*
K243921

Device Name
LED Curing Lights (DB686 HALO)

Indications for Use *(Describe)*
For dental clinics treatment to irradiate polymer-based restorative materials to cure them.
The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

510(k)#: K243921

Prepared on: 2025-04-11

1. Contact Details

Applicant Name: Foshan COXO Medical Instrument Co., Ltd.

Applicant Address: No.17,Guangming Ave.,New Light Source Industrial Base, Nanhai National High-tech Zone, Foshan 528226,Guangdong P.R. China

Applicant Contact Telephone: +86-13924548832

Applicant Contact: Mr. Zhaorong Li

Applicant Contact Email: lizhaorong@coxotec.cn

2. Device Name

Device Trade Name: LED Curing Lights

Model: DB686 HALO

Common Name: Ultraviolet activator for polymerization

Classification Name: Activator, Ultraviolet, For Polymerization

Device Class: Class II

Panel: Dental

Regulation Number: 21 CFR Part 872.6070

Product Code(s): EBZ, EAQ

Submission Type: Traditional 510(K)

3. Legally Marketed Predicate Devices

Primary Predicate Device

510(k) Number: K220826

Product Name: LED Curing Light (Model: DB686 NANO, DB686 SWIFT)

Product Code: EBZ

Secondary Predicate Device

510(k) Number: K220471

Product Name: VALO™ X; VALO™ X Accessory Lenses

Product Code: EBZ, EAQ, PEQ

Reference Device 1#

510(k) Number: K221194

Product Name: LEDEX WL-120

Product Code: EBZ

Reference Device 2#

510(k) Number: K221152

Product Name: CuringPen Dental Curing Light

Product Code: EBZ

4. Device Description

The LED Curing Lights (Model: DB686 HALO) is an oral device for repairing teeth. It uses the principle of light curing to make the dental repair resin material solidify rapidly under the action of light wave in the specific wavelength range (385~515nm), so as to fill the tooth cavity or bond the bracket. It is a cordless pen-style device, and consists of handpiece, LED cure tip, charging base, power adapter, eyes protector, eye protector unit and disposable protective sleeve.

The LED Curing Lights protects the handpiece and LED cure tip from gross contamination and prevent cross infection between patients by applying the disposable protective sleeve. The disposable protective sleeve (patient contact part) is made of PP material.

5. Intended Use/Indications for Use

For dental clinics treatment to irradiate polymer-based restorative materials to cure them.

The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.

6. Comparison to the Predicate Device

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
Product Code	EBZ, EAQ	EBZ	EBZ, EAQ, PEQ	EBZ	EBZ	NOTE 1
Regulation Number	21 CFR 872.6070	21 CFR 872.6070	21 CFR 872.6070	21 CFR 872.6070	21 CFR 872.6070	SE
Indications for Use	For dental clinics treatment to irradiate polymer-based restorative materials to cure them. The instrument must only be used in hospital environments, clinics or dental offices, by qualified practitioners.	For light curing polymerization of dental composites, luting materials, cements and other light cured materials.	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	LEDEX WL-120 is a visible curing unit programmed for polymerization of dental light cured materials by dental professionals.	The CuringPen Dental Curing Light is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photopolymerized in the 380~515nm waveband of visible light. This device must only be used in hospital	SE

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
			complete cure of photo-activated materials and adhesives.		environments, clinics or dental offices by qualified dental personnel and not used in oxygenrich environment.	
Principles of operation	1. Clean and disinfect all the surfaces of handpiece and tip before each use. 2. Cover the LED Cure Tip and handpiece with the Disposable Protective Sleeve. 3. Select curing mode and cure times/ orthodonticcycle(s) . 4. Short press ON/OFF Button to start working.	**DB686 NANO** 1. Clean and disinfect all the surfaces of handpiece and tip before each use. 2. Cover the Cure Tip and handpiece with the Disposable Protective Sleeve. 4. Operate the rotary switch to Cure. Press the Start key to activate light. Press once or Double press to	/	/	Step-by-step: 1. Disinfect contaminated surfaces of the light source head, protective light shield, handpiece before each use. 2. Make sure that the stipulated light irradiance permits adequate polymerization. For that purpose, check the light source head for contamination	SE

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
	5. Once the selected curing time has elapsed, the curing program is automatically terminated.	select curing time . 5. Once the selected curing time has elapsed, the curing program is automatically terminated. **DB686 SWIFT** 1. Clean and disinfect all the surfaces of handpiece and tip before each use. 2. Cover the Cure Tip and handpiece with the Disposable Protective Sleeve. 3. Select curing mode and cure times/ orthodonticcycle(s) . 4. Short press			and damage, as well as the light irradiance at regular intervals. 3. Select curing program and time 4. Start: Once the selected curing time has elapsed, the curing program is automatically terminated.	

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
		Power/Start Button to start working. Once the selected curing time has elapsed, the curing program is automatically terminated.				
Operational modes	A. Resin Curing: Cure the composite resin. Low-temperature Mode: Variable illumination output with illumination values pulsed at 800/1300 mW/cm^2 cycles; Normal Mode: Light output at a constant illumination of 1000mW/cm^2 for	**DB686 NANO** 1 programs: Curing light Mode:10s, 20s(1600 ~ 1800mW/cm^2) **DB686 SWIFT** 3 programs: - Soft up mode: 5s, 10s, 15s, 20s (1600mW/cm^2) - High power mode:	**Operational Modes (Curing EBZ)** VALO X: Standard Power Mode: 1,100 mW/cm^2 Xtra Power Mode: 2,200mW/cm^2 VALO X Accessory Lenses: ≥800 mW/cm^2 (PointCure –	**Operational modes** Low, Ramp, Standard, High, Turbo, Plasma, White **Light intensity** MAX. 3200 mW/cm^2	1) Standard mode: -2300 mW /cm^2 -1500 mW/cm^2 -1000 mW/cm^2 2) RAMP mode: 1000 mW/cm^2 3) PULSE mode: 1000 mW/cm^2 4) Detect mode: 600 mW/cm^2	NOTE 2

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
	conventional resin curing; Turbo Mode: Light output at a constant illumination of 3000mW/cm^2 for fast resin curing; B. Orthodontics Mode: mainly used for bracket bonding, the illumination value is about 3000mW/cm^2 ; work 3s stop 2s for a cycle, work cycle 1-8 times adjustable. C. Caries detection Mode: using violet light to irradiate the teeth to produce a fluorescent reaction, checking dental caries or dental	5s (1700mW/cm^2) - Orthodontic mode: 1-8Cycles (1800mW/cm^2)	Recommened with High Power Mode) (ProxiCure – Recommended with mode suitable for material) **Operational Modes (Diagnostic EAQ, PEQ)** VALO X Accessory Lenses: ≥25 mW/cm^2, ≤420 nm wavelength (Diffuser Lens – Black Light Diagnostic Aid Mode) ≥1,000 lx luminescence, 3,800-6,500 K color temperature, ≥75 CRI (Diffuser Lens –			

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
	calculus, a single working time of 60s.		White Light Diagnostic Aid Mode) ≥15,000 lx luminescence (Interproximal Lens – Recommended with Standard Curing mode) ≥500 nm wavelength (Translume Lens, any mode)			
Light source	10W LED blue and violet	10W LED	LED light, blue and violet wavelengths (Curing mode) LED light, violet or white wavelengths (Diagnostic mode) 12.5mm head size	10W LED	10W LED	SE

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
Power source	Power adapter Input: 100-240V ~ 50/60Hz Output: 5V ⎓ 2A Li-ion battery: 3.7V 800mAh	Adapter: 100V - 240V~ 50 - 60 Hz Output: 5V ⎓ 1.5A Batterycharging	VALO X curing light can be powered by an AC power supply or rechargeable batteries. **AC Power Supply:** Wall powered. Output: 9VDC, 2.0A. Input: 100VAC - 240VAC, 50-60 Hz with adapters for international capability. Ratings: Medical Grade, (CE, RoHS, REACH) Cord: 6 ft (1.8m), 2.5mm DC connector **Battery Power:** 1IMR14/65 3.7V 900mAh 3.33 Wh Li Ion rechargeable	**Power supply** Input: AC100~240V, 50/60Hz Output: DC 5V/2A **Power source** 3.7V Rechargeable Li-ion battery	3.7V DC with Lithium ion battery 5V DC with charger power	NOTE 3

Item LED Curing Lights	Proposed Device LED Curing Light (K220826)	Primary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Secondary Predicate Device	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
			battery pack **Power On Button:** Located on the handle of the wand, back side and front side			
Accessories	-Handpiece -Charging Base -LED cure tip -Battery (Included in the handpiece) -Eyes protector -Power adapter -Disposable protective sleeve -Eye protector unit -User Manual	**DB686 NANO** -Handpiece -Charging Base -Cure Tip -Protection glasses -Battery pack -Adapter (with Power Cord) -Protective Sleeve -User Manual **DB686 SWIFT** -Handpiece	-Barrier Sleeve VALO™, -Blue-Light Blocking Light Shield -PointCure Lens, ProxiCure Ball Lens, Translume Lens, Diffuser Lens, Inter-proximal Lens,	Handpiece, Power supply, Optical fiber light guide rod, Filter, Light guide sleeves, Cradle, Anti-glare shield	-Handpiece -Charging base -Light source head -Protective light shield -Adapter -Disposable sleeves (1x100pcs) -User Manual Optional accessories: -Light curing depth test board -Protective light	NOTE 4

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
		-Charging Base -Cure Tip -Battery (Included in the handpiece) -Adapter (with Power Cord) -Protective Sleeve -User Manual			glasses	
Use	Prescription / Hospital	Prescription / Hospital	Prescription / Hospital	Prescription / Hospital	Prescription / Hospital	SE
Wavelength range	385~515nm	385-515nm	380–515 nm	390nm-480nm	380-515nm	SE
Peak wavelength (nm)	402 & 460nm	460nm	**VALO X:** Nominal values: 380-420nm and 420-515nm **VALO X Accessory Lenses:**	405 & 460 nm	Dual peak: 400-410nm, 450-460nm	NOTE 5

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
			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)			
Composition of patient-contacting portions of device	Disposable protective sleeve, material: PP	Disposable protective sleeve, material: PP	Barrier Sleeve	Light guide sleeves	Disposable sleeve	SE
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	SE
Infection Control	Use disposable protective sleeve and surface disinfection	Use disposable protective sleeve and surface disinfection	Barrier Sleeve	Light guide sleeves	Use disposable sleeve to prevent cross infection of the	SE

Item	Proposed Device LED Curing Lights	Primary Predicate Device LED Curing Light (K220826)	Secondary Predicate Device VALO™ X; VALO™ X Accessory Lenses (K220471)	Reference Device 1# LEDEX WL-120 (K221194)	Reference Device 2# CuringPen Dental Curing Light (K221152)	Remark
	to prevent cross infection of the patient.	to prevent cross infection of the patient.			patient	
Electrical Safety	IEC60601-1 IEC60601-1-2 ANSI AAMI ES60601-1 ANSI AAMI ES60601-1-2 IEC 80601-2-60	IEC60601-1 IEC60601-1-2 IEC 80601-2-60	IEC 60601-1 IEC 60601-1-2 IEC 80601-2-60	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2 ANSI AAMI ES60601-1	NOTE 6
Photobiological Safety	IEC 62471	IEC 62471	IEC 62471	/	IEC 62471	SE
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-11	ISO 10993-5 ISO 10993-10 ISO 10993-11	ISO 10993-1	/	ISO 10993-5 ISO 10993-10	SE

Note:

Note 1 The curing function of proposed device is conformed with product code EBZ (K220826, K220471) and the detect function is conformed with product code EAQ (K220471), but PEQ is not applicable.

Note 2 The operational modes and light intensity of the proposed device is different with the predicate device. The proposed devices have several modes corresponding to the light output intensity and available times.

The maximum light intensity of the proposed device is higher than the predicate device which can achieve higher efficiency for irradiating polymer-based restorative materials, but it is still lower than a reference device K221194 (the claimed maximum light intensity is Max. 3200mW/cm^2).

The light output safety and performance test was conducted according to ISO 10650, IEC 62471, IEC 60601-1 and FDA guidance performance testing requirements.

The testing results show that these difference do not affect the safety and effectiveness .

Note 3 The proposed device is charged by the contact charging method as same as the primary predicate device. As a power source for the charger, the AC/DC adapter provided by the manufacturer is used. The input specifications of the adapter (100-240VAC, 50-60Hz) are the same, but the outputs differ from each other at 5V ⎓ 2A and 5V ⎓ 1.5A respectively. These difference do not the affect safety and effectiveness.

Note 4 In order to block the blue light radiation outside the application part to protect the eyes of the operator and patient from blue light hazard, the proposed device provides two accessories: Eyes protector and Eye protector unit, and the predicate device only has Protection glasses which is same with Eyes protector. Eye protector unit provides an additional solution to protect the eyes of dentists and patients from hurting.

This difference does not affect the safety and effectiveness.

Note 5 The proposed device and the secondary predicate device have dual peak wavelength. The peak wavelength of the proposed device is described as given values while the peak wavelength of reference device as a range. The values are similar. This difference does not raise issues of substantial equivalence.

Note 6	According to the requirements of US national differences, the proposed device has tested by ANSI AAMI ES60601-1 and ANSI AAMI ES60601-1-2. Different but does not adversely impact safety and effectiveness of proposed device.	

Discussing:

The new device LED Curing Lights (Model: DB686 HALO) is substantial equivalence as the primary predicate device K220826, the secondary predicate device K220471 and the reference devices (K221194, K221152). The differences was in model and some minor parameters, it's because of they are different in design requirements between different devices, which not affect the safety performance of the device, and the new device passed Safety testing, so these differences will not cause any safety and effectiveness issues. Considering the same intended use/indications for use, principles of operation, and product performance etc., they are substantial equivalence.

7. Non-clinical Data

All nonclinical testing performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing demonstrate the compliance to the standards and matching the performance of new devices to the predicate devices.

- ISO 10993-5:2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- IEC 60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- AAMI ES60601-1:2021 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2:2020 Medical electrical equipment - Part 1-2: General requirements for basic

safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

- ANSI/AAMI/IEC 60601-1-2:2021 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- IEC 62471: 2006 Photobiological safety of lamps and lamp systems
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 2: Lithium systems
- ISO 10650:2018 Dentistry — Powered polymerization activators
- ISO 4049:2019 Dentistry - Polymer-based restorative materials

8. Clinical Data

There were no clinical tests performed for the LED Curing Lights (Model: DB686 HALO).

9. Conclusion

The LED Curing Lights (Model: DB686 HALO) is substantially equivalent to the primary predicate device (K220826), secondary predicate device (K220471) and the reference devices (K221194, K221152).