



April 10, 2025

Premium Plus (Dongguan) Limited
Jessica Mao
Regulatory Affairs Manager
Flat 101, No.122, Tianqiao Road, Changping
Dongguan, Guangdong 523581
China

Re: K250009
Trade/Device Name: LED Curing Light (C01-X, C02-X)
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: March 18, 2025
Received: March 18, 2025

Dear Jessica Mao:

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
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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

Indications for Use

Submission Number (if known)

K250009

Device Name

LED Curing Light (C01-X, C02-X)

Indications for Use (Describe)

LED Curing Light is intended for use by trained dental professionals only for the purpose of light curing dental resins and composites.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Premium Plus (Dongguan) Limited
Applicant Address	Flat 101, No.122, Tianqiao Road, Changping, Dongguan, Guangdong 523581, China Dongguan 523581 China
Applicant Contact Telephone	86 769 83397277
Applicant Contact	Ms. Jessica Mao
Applicant Contact Email	jessicamao@premiumplushk.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	LED Curing Light (C01-X, C02-X)
Common Name	Ultraviolet activator for polymerization
Classification Name	Activator, Ultraviolet, For Polymerization
Regulation Number	872.6070
Product Code(s)	EBZ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K153514	Premium Plus C01/C02 LED Curing Light	EBZ
K221194	Ledex WL-120	EBZ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

LED Curing Light is classified as an Ultraviolet Activator for Polymerization (21 CFR 872.6070). It is used for polymerization of dental light cured materials by dental professionals. The device is based on blue LED (light emitting diode) technology. It has four curing modes. Using different modes gives dental professionals the flexibility to polymerize virtually dental resins and composites.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

LED Curing Light is intended for use by trained dental professionals only for the purpose of light curing dental resins and composites.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indications for use of LED Curing Light are the same as the predicate device, Premium Plus C01/C02 LED Curing Light(K152514).

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The subject device and the predicate device are both LED curing lights for dental composites or resins. The indications for use and technological characteristics are substantially equivalent with only minor differences. These minor differences do not constitute a new intended use or raise different issues of safety and effectiveness compared with the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

Performance testing was conducted to meet the requirements in Guidance for Industry and FDA Staff -Dental Curing Lights- Premarket Notification [510(k)] Submission.

Non-clinical testing performed to establish substantial equivalence to the predicate device including radiant power output testing(ISO 10650), heat generation, depth of cure, electrical safety(IEC 60601-1 and IEC 80601-2-60), and EMC(IEC 60601-1-2 and IEC 60601-4-2).

Not Applicable

Based on the non-clinical tests, the proposed LED Curing Light is as safe, as effective, and performs as well as or better than the predicate device Premium Plus C01/C02 LED Curing Light(K153514).