



Food and Drug Administration
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August 22, 2016

Premium Plus International Limited
Jessica Mao
QA Engineer
Flat 1001 Yuen Long Trading Centre, 33 Wang Yip Street West, Yuen Long, N.T.
Hong Kong
CHINA

Re: K153514

Trade/Device Name: Premium Plus C01/C02 LED Curing Light
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: July 7, 2016
Received: July 14, 2016

Dear Ms. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Michael J. Ryan -S

for Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

PREMIUM PLUS INTERNATIONAL LIMITED

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Section 5 510(k) Summary **[As Required by 21 CFR 807.92]**

510(k) Number: K153514

Submitter: Premium Plus International Limited
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No. 33 Wang Yip Street West,
Yuen Long, N.T. Hong Kong, China
(Establishment registration number: 3006847937)

Contact Person: Jessica Mao
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Device Name: Activator, Ultraviolet, For Polymerization
Trade Name: Premium Plus C01/C02 LED Curing Light
Common Name: Dental Curing Light
Model Type: C01 & C02 (As they have same design requirements, performance specifications, technology, intended use and similar indications, they are summarized into one 510(k) submission, adherence to Section 4 of the guidance document for Bundling Multiple Device or Multiple Indications in a Single Submission)

Device Panel: Dental
Basis for Submission: New Device
Regulation Name: Ultraviolet Activator for Polymerization
Device Classification: Class II
Regulation Number: 21 CFR 872.6070
Regulation Description: Ultraviolet activator for polymerization
Product Code: EBZ

(A) Primary Predicate Device to Premium Plus C01 LED Curing Light:

Trade Name: Ledex WL-070
510(k) Number: K082408
Manufactured by: Dentmate Technology Company, Limited

(B) Primary Predicate Device to Premium Plus C02 LED Curing Light:

Trade Name: Coltolux® LED Curing Light
510(k) Number: K040551
Manufactured by: Coltene/Whaledent Incorporated

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(C) Reference Device for Performance Testing to Premium Plus C02 LED Curing Light:

Trade Name: VALO® Cordless
510(k) Number: K110582
Manufactured by: Ultradent Products, Inc.

Device Description:

Premium Plus C01/C02 LED Curing Light is classified as an Ultraviolet Activator for Polymerization (21 CFR 872.6070) because 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 three curing modes. Using different modes gives dental professionals the flexibility to polymerize virtually almost all types of composites, bonding agents and sealants available in the market.

Premium Plus C01/C02 LED Curing Light consists of a handpiece and a charging station, which is connected via a plug-in transformer to an AC outlet for charging. The handpiece contains high intensity dental blue LED light source and a fibre optic light guide(C01-1) that conduct light to the treatment area on the patients or direct light source head(C02-1). A protective light shield and transformer are accessories provided with Premium Plus C01/C02 LED Curing Light, which support the operation of the device. The protective light shield filters blue light to protect eyes of dental professionals and patients. An FDA cleared barrier sleeves must be used between each patient such as the Pac-Dent Barrier Sleeve.

Indications for Use:

Premium Plus C01/C02 LED Curing Light is intended for use by trained dental professionals for the purpose of curing dental composites by light.

Technological Characteristics and Substantial Equivalence:

Table 1: Comparison of the Proposed Device Premium Plus C01 LED Curing Light against the Predicate Device Ledex WL-070

Device	Ledex WL-070 510(k) Number:K082408	Premium Plus C01 LED Curing Light
Intended Use	Used by trained dental professionals to polymerize dental light cured materials	Same
Target Users	Professional Dentists and Hygienists	Same
Light Source	LED light	Same
Operational Modes	3 modes: Full, Ramp, Pulse	Same
Power Source	3.7V, 800mAh, Lithium-ion type	3.7V, 1100 mAh, Lithium - ion type
Power Supply	Input: AC100~240V, 50/60Hz Output: DC 5V/2A	Input: AC 100-240V, 50/60Hz

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		Output: DC 5V/1A (with charging station)
The Range of Wavelength	440nm~480nm, peak:460nm	Same
Radiant Intensity	1100 mw/cm ² - 1200 mw/cm ²	750 mw/cm ² - 1200 mw/cm ²
Light Guide Rod	Ø8mm Optical fiber sterilization in autoclave	Same
Operating Environmental Factors	10°C~40°C/30%~75%relative humidity/500hPa~1060hPa atmospheric pressure	Same
Handpiece Size	Ø2.6cm x 15.6cm	Ø2.7cm x 24cm
Weight	120g	160g
FDA- Recognized Standards	EN60601-1	IEC 60601-1:2005 IEC 60601-1-2:2007 ISO 10650-2:2007

Premium Plus C01 LED Curing Light and its predicate device Ledex WL-070 have identical intended use, operational principles and performance specifications. They also both transmit visible blue LED light at wavelength known to polymerize the dental resins. The devices are substantially equivalent in intended use, operation, wavelength range, light intensity, and light source.

Table 2: Comparison of the Proposed Device Premium Plus C02 LED Curing Light against the Predicate Device Coltolux® LED Curing Light

Device	Coltolux® LED Curing Light 510(k) Number:K040551	Premium Plus C02 LED Curing Light
Intended Use	Used by trained dental professionals to polymerize dental light cured materials	Same
Light Source	LED Light	Same
Operational Modes	1mode: Ready mode	3 modes: Full, Ramp, Pulse
Power Source	Rechargeable battery	3.7V, 1100 mAh, Lithium - ion type
Radiant Intensity	300 mw/cm ² or higher	750 mw/cm ² - 1200 mw/cm ²
Accessories	Snap on light shields, barrier sleeves, light lenses, goggles, test block, adapter	Protective light shield, caps, head protective rings, adapter
Operating Environmental Factors	10°C~40°C / relative humidity 80% at 25°C	10°C~40°C / 30%~75% relative humidity / 500hPa~1060hPa atmospheric pressure
FDA- Recognized Standards	IEC60601-1-2	IEC 60601-1 IEC 60601-1-2 ISO 10650-2:2007

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Premium Plus C02 LED Curing Light and its primary predicate device Coltolux® LED Curing Light have the same intended use and light source. They both have the similar product appearance and power source, and require the similar operating environmental factors. Furthermore, they both are electrical safety and electromagnetic compatibility in accordance with IEC 60601-1-2.

Performance Test:

The following tests were conducted to evaluate the functional performance and safety of Premium Plus C01/C02 LED Curing Light:

- Electrical Safety
- Electromagnetic Compatibility
- Light-emitting diode(LED) lamps
- Depth of Cure

The test results confirm that Premium Plus C01/C02 LED Curing Light conforms to the requirements in ISO 60601-1, ISO 60601-1-2 and ISO 10650-2 / ANSI/ADA Specification No. 48-2, LED Curing Lights, and is substantially equivalent for use as a dental curing light.