July 3, 2019

Ivoclar Vivadent, AG
% Lori Aleshin
Director of Quality & Regulatory Affairs
Ivoclar Vivadent, Inc.
175 Pineview Drive
Amherst, New York 14228

Re: K190272
Trade/Device Name: Bluephase PowerCure
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: June 11, 2019
Received: June 13, 2019

Dear Lori Aleshin:

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,

Srinivas Nandkumar, Ph.D.
Acting Assistant Director
DHT1B: Division of Dental 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
**K190272**

Device Name
Bluephase® PowerCure

Indications for Use *(Describe)*
With its "Polywave" LED with broadband spectrum, Bluephase PowerCure is suitable for the polymerization of all light-curing dental materials curing in the wavelength range of 385 – 515 nm. These materials include restoratives, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations, such as ceramic inlays.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) SUMMARY

# K190272



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Date Prepared: June 6, 2019

**Proprietary Name:** **Bluephase® PowerCure**

**Classification Name:** Activator, Ultraviolet, For Polymerization (872.6070)
(Classification Code EBZ)

**Predicate Device:** Bluephase Style 20i (K163613) by Ivoclar Vivadent, AG

**Device Description:** **Bluephase® PowerCure** is an LED curing light that produces blue light. It is used for the polymerization of light-curing dental materials immediately in the oral cavity of patients. The intended place of application is in the dental practice, medical practice or in the hospital by the dentist or dental assistant. The curing light must only be operated by trained dental personnel.

- The handpiece has the shape of a pen
- Operational notes: 4 programs (3s, Turbo, High, PreCure)
- Light source: Polywave LED
- Power Source: Li-Ions battery

**Indications for Use:** With its "Polywave" LED with broadband spectrum, Bluephase PowerCure is suitable for the polymerization of all light-curing dental materials curing in the wavelength range of 385 – 515 nm. These materials include restoratives, bonding agents/adhesives, bases, liners, materials include restoratives, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations, such as ceramic inlays.

**Comparison to Predicate:** The primary predicate devices to which Bluephase® PowerCure has been compared is Ivoclar Vivadent, AG Bluephase Style 20i (K163613). The new device Bluephase PowerCure composite materials can be cured within 3 seconds, the new device is able to emit light with an irradiance of 3,050 mW/cm$^2$ in contrast to the predicate and has 4 curing modes in contrast to 2 programs of the predicate. To enable the higher light irradiance the power supply has a higher output.

**Reference Device:** VALO Grand Corded manufactured by Ultradent Products Inc. (K190627)

| Device | Ivoclar Vivadent AG: Bluephase Style 20i (K163613) | Ivoclar Vivadent: Bluephase® PowerCure |
|---|---|---|
| **Indications for Use** | With its "Polywave" broadband spectrum, Bluephase Style 20i is suitable for the polymerization of all light curing dental materials curing in the wavelength range of 385-515 nm. These materials include restoratives, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations, such as ceramic inlays. | With its "Polywave" LED with broadband spectrum, Bluephase PowerCure is suitable for the polymerization of all light-curing dental materials curing in the wavelength range of 385 – 515 nm. These materials include restoratives, bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations, such as ceramic inlays. |
| **Summary of Indications** | The indications are the same as for the predicate therefore both devices are substantially equivalent. | |
| **Principles of operation** | **Step-by-step:**<br>1. Disinfect contaminated surfaces of the curing light as well as light probes and anti-glare cones before each use.<br>2. Make sure that the stipulated light irradiance permits adequate polymerization. For that purpose, check the light probe for contamination and damage, as well as the light irradiance at regular intervals.<br>3. Select curing program and time<br>4. Start: Once the selected curing time has elapsed,the curing program is automatically terminated. | **Step-by-step:**<br>1. Disinfect contaminated surfaces of the curing light as well as light guides and anti-glare cones before each use.<br>2. Make sure that the stipulated light irradiance permits adequate polymerization. For that purpose, check the light probe for contamination and damage, as well as the light irradiance at regular intervals.<br>3. Select curing program and time<br>4. Start: Once the selected curing time has elapsed, the curing program is automatically terminated. |
| **Summary Principles of operation** | No difference. | |
| **Delivery form content** | 1 Charging base with power cord and power pack<br>1 Handpiece<br>1 Light probe 10>8 mm, black<br>1 Anti-glare shield<br>3 Anti-glare cones<br>1 Pack of sleeves<br>1 Instructions for use | 1 Charging base with power cord and power pack<br>1 Handpiece<br>1 Handpiece support<br>1 Light guide 10>9 mm<br>1 Anti-glare shield<br>3 Anti-glare cones<br>1 Instructions for Use |
| **Summary of Delivery form content** | The US delivery form currently does not contain sleeves. Customers are recommended to use an alternative product which is locally available in the US.<br>The handpiece support is an accessory so that the dentist can lie the device down without putting it on the charging base or the working surface.<br>The differences in the light guide diameter is non-significant.<br>Therefore, delivery forms are basically the same for both devices. | |
| **Electrical Safety** | This product has been tested to IEC 60601-1:2005 and IEC 60601-1-2:2007 | The new device has been tested to IEC 60601-1:2012 and IEC 60601-1-2:2007 |
| **Summary of Electrical Safety** | Bluephase PowerCure conforms to the current version of the same standards as the predicate device. | |

| | | |
|---|---|---|
| **Operational modes** | 2 programs:<br>- Turbo (2,000 mW/cm$^2$)<br>- High Power Program (1,200 mW/cm$^{2)}$ | 4 programs:<br>- 3s Cure Program (3,050 mW/cm$^2$)<br>- Turbo program (2,100 mW/cm$^2$)<br>- High power Program (1,200 mW/cm$^2$)<br>- PreCure (preset to 2s)(950 mW/cm$^2$) |
| **Summary Operational modes** | The innovation of the new device Bluephase PowerCure is that it is able to emit light with 3,050mW/cm$_2$ in combination with a shorter curing time. | |
| **Storage Conditions** | Temperature: -20 °C to + 60 °C /+4 °F to +140 °F<br>Relative humidity: 10% to 75% | Temperature: -20 °C to + 60 °C /+4 °F to +140 °F<br>Relative humidity: 10% to 75% |
| **Summary of Storage Conditions** | No difference. | |
| **Device Specification Summary** | The higher irradiance of Bluephase PowerCure (3,050mW/cm$^2$) is comparable to the Xtra Power Mode (3,200 mW/cm$^2$) | |

**Infection Control:**
The device is sold in a non-sterile condition. Prior to use and after use sterilization of the light probe is recommended. The sterilization cycle recommended in the Instructions for Use have been validated according to ISO 14937 Sterilization of health care products- General requirements for characterization of a sterilization agent and the development, validation and routine control of a sterilization process for medical devices.

**Biocompatibility**:
Direct contact with tissue is not intended. Therefore ISO 10993-1 is not applicable. A Toxicological statement of the light tip of the LED Unit Bluephase PowerCure has been included in this submission.

**Software Validation:**
Bluephase PowerCure software/firmware has been fully validated and the device software meets its Design Specifications. FDA Guidance Document Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices has been followed in connection with the design of the device.

**Summary of Safety Testing:**
The product has been tested to IEC 60601-1:2012 and IEC 60601-1-2:2007 and meets the requirements for Electrical Safety, including US National Deviations, and Electromagnetic Compatibility. The test reports are included in this submission.

**Conclusion:**
Bluephase PowerCure is an LED polymerization light, which is used for the polymerization of light-curing dental materials. This is achieved by using the same operating principle and performance criteria as for Bluephase Style 20i.

Therefore, Bluephase PowerCure is substantially equivalent to its predicate device, Bluephase Style 20i.