DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ivoclar Vivadent, AG
% Donna Hartnett
Director QA/ Regulatory Affairs
Ivoclar Vivadent, Inc
175 Pineview Drive
Amherst, New York 14228

April 4, 2017

Re: K163613
Trade/Device Name: Bluephase Style 20i
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: January 4, 2017
Received: January 5, 2017

Dear Donna Hartnett:

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" (21 CFR 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,

Susan Runner DDS, MA

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
Bluephase® Style 20i

Indications for Use *(Describe)*
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.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) SUMMARY

Bluephase® Style 20i

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, AG
Bendererstrasse 2, Schaan, FL-9494, Liechtenstein
+423-235-3535

Date Prepared: December 19, 2016

Proprietary Name: Bluephase® Style 20i
Classification Name: Activator, Ultraviolet, for Poymerization 872.6070
(Classification Code EBZ)

Predicate Device: Bluephase 20i - K091020

Device Description: Bluephase® Style 20i is an LED polymerization light that produces energy-rich blue plight. It is used for the polymerization of light-curing dental materials immediately at the dental unit. It consists of 1 Polywave LED in the probe.

- ☐ The handpiece has the shape of a pen
- ☐ Operational notes: 2 programs (Turbo, High Power)
- ☐ Light source: Polywave LED
- ☐ Power source: Li-Po battery

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.

Comparison to Predicate: Both dental curing lights are indicated for light curing of dental restoratives including bonding agents/adhesives, bases, liners, fissure sealants, temporaries, as well as luting materials for brackets and indirect restorations, such as ceramic inlays. In the case of Bluephase® Style 20i, the design has 2 programs (Turbo, High Power).

# 510(K) SUMMARY

Bluephase® Style 20i

| Indications for Use | Predicate device K091020 | Bluephase® Style 20i |
|---|---|---|
| Indications | For light curing polymerization of light-curing dental materials curing in the wavelength range of 385–515 nm. These materials include restoratives, bonding agents/ adhesives, bases, liners, fissure sealants, temporary materials as well as luting materials for brackets and indirect restorations such as ceramic inlays. | 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. |
| Summary Indications | Bluephase® Style 20i is an LED polymerization light that produces energy-rich blue light. It is used for the polymerization of light-curing dental materials immediately at the dental unit. This is achieved using the same technology as the predicate device Bluephase® 20i. Furthermore, Bluephase® Style 20i features 2 programs instead of the 4 programs that are part of the predicates design.<br><br>Therefore, Bluephase® Style 20i is substantially equivalent to the predicate device, Bluephase 20i® Plus. | |

# 510(K) SUMMARY

Bluephase® Style 20i

| | | |
|---|---|---|
| Working Principle | 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 intensity permits adequate polymerization. For that purpose, check the light probe for contamination and damage, as well as the light intensity 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 probes and anti-glare cones before each use.<br>2. Make sure that the stipulated light intensity permits adequate polymerization. For that purpose, check the light probe for contamination and damage, as well as the light intensity 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 Working Principle | No difference. | |
| Summary Material Composition | No difference | |
| Power Output | ☐ 650 mW/cm$^2$ (5 sec) then ramps to 1,200 mW/cm$^2$ (10, 15, or 20 sec)<br>☐ Low – 650 mW/cm$^2$ (10, 15, or 20 sec)<br>☐ High 1,200 mW/cm$^2$(10, 15, or 20 sec)<br>☐ Turbo 2,000 mW/cm$^2$ (5 sec) | ☐ High 1,200 mW/cm$^2$ (10, 15, or 20 sec)<br>☐ Turbo 2,000 mW/cm$^2$ (5 Sec) |
| Design styling | Wand Style | Gun style |
| Electrical Safety | The product has been tested to IEC 60601-1:2005 and IEC 60601-1-2:2007 | This product has been tested to IEC 60601-1-: 2005 and IEC 60601-1-2: 2007 |
| Summary of Electrical Safety | Bluephase® Style 20i conforms to the current version of the same standards as the predicate device. | |

# 510(K) SUMMARY

Bluephase® Style 20i

## Summary of Safety Testing:

The product has been tested to IEC 60601-1:2005 and IEC 60601-1-2:2007 and meets the requirements for Electrical Safety, including US National Deviations, and Electromagnetic Compatibility. The Bluephase Style 20i was bench tested to assure the switch-off temperature of the heat sink functioned properly and found to meet the design specifications.

## Software Validation:

Bluephase Style 20i software/firmware has been fully validated and the device software meets its Design Specifications. FDA Guidance Document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005) has been followed in connection with the design of this device.

## Biocompatibility:

The Bluephase Style 20i has been evaluated for biocompatibility and compared to the predicate device. No new issues of biocompatibility are related to the subject device as the construction materials are substantially the same.

## 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 DIN EN 556-1: Sterilization of a Medical Device and ISO 17665-2:2009. The curing light also is sold with plastic sleeves for infection control.

## Conclusion:

Bluephase® Style 20i is a LED polymerization light that is used for the polymerization of light-curing dental materials. This is achieved using the same operating principle and performance as the one used in Bluephase® 20i. Furthermore, Bluephase® Style 20i comes in a new wand shape design. The working steps and indications for use are the same as with Bluephase® 20i.

Therefore, Bluephase® Style 20i is substantially equivalent to the predicate device, Bluephase® 20i.