



JUN 12 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Donna Marie Hartnett
Director, Assistant Corporate Counsel
Ivoclar Vivadent, Incorporated
175 Pineview Drive
Amherst, New York 14228

Re: K091020
Trade/Device Name: bluephase® 20i
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: April 7, 2009
Received: April 29, 2009

Dear Ms. 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Susan Runner, D.D.S.

Acting Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091020

Device Name: bluephase® 20i
Indications For Use:

For the polymerization of light-curing dental materials curing in the wavelength range of 380-515 nm.

Prescription Use AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Kevin Mulvey for MSN
Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off) Page 1 of _____
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091020