



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Konstantinos Kyritsis, PH.D.
Research and Development Manager
DMP, Limited
Kalyvion Avenue
Markopoulo Industrial Zone
Attiki, 19003
GREECE

SEP 28 2012

Re: K121915

Trade/Device Name: Bright Restorative Materials (Nanocream-Bright Flow, Bright Flow Core, Bright Heavy Core, Bright Light, Bright Light Flow, and Bright Posterior

Regulation Number: 21 CFR 872.3690

Regulation Name: Tooth Shade Resin Material

Regulatory Class: II

Product Code: EBF, EBC

Dated: May 28, 2012

Received: July 2, 2012

Dear Dr. Kyritsis:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 yours,



Anthony D. Watson, B.S., M.S., M.B.A.
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): K121915

Device Name: BRIGHT Restorative Materials, to include:

- **NANOCERAM – BRIGHT FLOW**
- **BRIGHT FLOW CORE**
- **BRIGHT HEAVY CORE**
- **BRIGHT LIGHT**
- **BRIGHT LIGHT FLOW**
- **BRIGHT POSTERIOR**

Indications for Use:

NANOCERAM – BRIGHT FLOW

Indications for use:

- Fillings of minimally invasive cavities of all classes
- Fillings of small class I cavities
- Fillings of class II-V cavities including V-shaped defects and cervical caries
- Extended fissure sealing
- Cavity lining – as the first layer for Class I and II restorations
- Splinting of mobile teeth
- Blocking out of undercuts
- Small restorations of all types
- Repair of composite restorations and ceramic veneers

BRIGHT FLOW CORE - BRIGHT HEAVY CORE

Indications for use:

- Core build up of vital and non-vital teeth
- Post cementation

BRIGHT LIGHT - BRIGHT LIGHT FLOW

BRIGHT LIGHT

Indications for use:

- Class I-V restorations
- Reconstruction of affected anterior teeth
- Veneering of discoloured anterior teeth
- Splinting of mobile teeth
- Repair of composite and ceramic veneers

BRIGHT LIGHT FLOW

Indications for use:

- Fillings of minimally invasive cavities of all classes
- Fillings of class II-V cavities including V-shaped defects and cervical caries
- Extended fissure sealing
- Splinting of mobile teeth
- Blocking out of undercuts
- Small restorations of all types
- Repair of composite restorations and ceramic veneers

BRIGHT POSTERIOR

Indications for use:

- Direct posterior restorations (Class I and II), including occlusal surfaces
- Core build ups
- Splinting of mobile teeth

Prescription Use X
(21 CFR Part 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR Part 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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