



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

Mr. Dimitris Prantsidis
DMP, Limited
2nd Km Kalyvion Avenue, Markopoulo Industrial Zone
Markopoulo
GREECE 19003

JAN 13 2011

Re: K102836

Trade/Device Name: BONASIL A⁺ Impression Materials, to include:

- BONASIL A⁺ Putty: Putty normal set, Putty fast set, Putty soft, Putty extra hard, Lab Putty
- BONASIL A⁺ Heavy: Heavy normal set, Heavy fast set
- BONASIL A⁺ Monophase: Monophase normal set, Monophase fast set
- BONASIL A⁺ Regular: Regular normal set, Regular fast set
- BONASIL A⁺ Light: Light normal set, Light fast set
- BONASIL A⁺ Bonabite: Bonabite fast set
- BONASIL A⁺ Alginate Free: Alginate free normal set, Alginate free fast set

Regulation Number: 21 CFR 872.3660

Regulation Name: Impression Material

Regulatory Class: II

Product Code: ELW

Dated: December 22, 2010

Received: December 22, 2010

Dear Mr. Prantsidis:

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.

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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

K102836

4. SECTION: Indications for Use Statement

Device name: **BONASIL A⁺ Impression Materials**, to include:

- **BONASIL A⁺ Putty**
 - Putty normal set
 - Putty fast set
 - Putty soft
 - Putty extra hard
 - Lab putty
- **BONASIL A⁺ Heavy**
 - Heavy normal set
 - Heavy fast set
- **BONASIL A⁺ Monophase**
 - Monophase normal set
 - Monophase fast set
- **BONASIL A⁺ Regular**
 - Regular normal set
 - Regular fast set
- **BONASIL A⁺ Light**
 - Light normal set
 - Light fast set
- **BONASIL A⁺ Bonabite**
 - Bonabite fast set
- **BONASIL A⁺ Alginate Free**
 - Alginate free normal set
 - Alginate free fast set

Intended use:

The *Bonasil A⁺ Impression Materials* are intended to:

- be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of a patient's teeth and gums;
- provide models for study and for production of restorative prosthetics devices;

Indications for use:

- **BONASIL A⁺ Putty** (putty normal set, putty fast set, putty soft, putty extra hard, lab putty) is to be used as a preliminary material for:
 - Two step putty/wash technique
 - Single step putty/wash technique
 - Functional peripheries
 - Crown/bridge work
 - Inlays, onlays

- **BONASIL A⁺ Heavy** (heavy normal set, heavy fast set) is to be used as a heavy body material for:
 - Two step putty/wash technique
 - Single step putty/wash technique
 - Functional peripheries
 - Crown/bridge work
 - Inlays, onlays

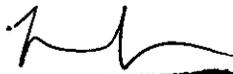
- **BONASIL A⁺ Monophase** (monophase normal set, monophase fast set) is to be used as a semi-heavy body material for:
 - Single step putty/wash technique
 - Functional peripheries
 - Crown/bridge work
 - Inlays, onlays

- **BONASIL A⁺ Regular** (regular normal set, regular fast set) is to be used as a medium body material for:
 - Two step putty/wash technique
 - Single step putty/wash technique
 - Functional peripheries
 - Reline impressions
 - Crown/bridge work
 - Inlays, onlays

- **BONASIL A⁺ Light** (light normal set, light fast set) is to be used as a light body material for:
 - Two step putty/wash technique
 - Single step putty/wash technique
 - Functional peripheries
 - Reline impressions
 - Crown/bridge work
 - Inlays, onlays

- **BONASIL A⁺ Bonabite** (bonabite fast set) is to be used as a light body material for:
 - Making accurate occlusal registrations
 - Standards bite registrations in the end bite position
 - Key material for needle point registration
 - Production of small model segments
 - An optical registration of occlusal data for CAD/CAM/CIM systems

- **BONASIL A⁺ Alginate free** (normal set, fast set) is an alternative to traditional alginate materials and is suitable for:
 - Preliminary impressions
 - Anatomic models
 - Fabricating temporary crowns and bridges
 - Opposing dentition
 - Fabricating simple removable prosthetic restorations
 - Orthodontic work
 - Case study models



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number R102836