510(k) Summary

MAY 30 2008

Trade Name: **Nanocomposite Restorative Kit**

Sponsor:

DMG USA, Inc.
23 Frank Mossberg Drive
Attleboro, MA 02703
Registration # not yet assigned
Owner/Operator No. 9005969

Device Generic Name: Nanocomposite Restorative Kit

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Product Description:
The Nanocomposite Restorative Kit consists of 3 materials:

Nanocomposite is indicated for

- Restorations of all cavity classes
- Fabrication of direct inlays, onlays and indirect veneers
- Core build-up after tooth preparation with the root canal post
- Machinable Composite for Restorations
- Indirect Inlays/Onlays

Nanocomposite Flowable is indicated for

- Small fillings of cavity classes III, IV and V
- Minimally invasive fillings for deciduous teeth (all cavity classes)
- Splinting of teeth

MDP One Bottle Bond is indicated for:

- Bonding resin-based materials (especially light-cure composite / compomer materials) to tooth structure (dentin and enamel)

Predicate Devices:
The components of the proposed Nanocomposite Restorative Kit materials are substantially equivalent to several currently marketed dental restorative materials including the following:

Nanocomposite:

Product Name	Predicates
SternOmega Composite LC	K982692 (Sterngold / Implamed)

Nanocomposite Flowable:

Product Name	Predicates
SternOmega Composite LC	K982692 (Sterngold / Implamed)

MDP One Bottle Bond:

Product Name	Predicates
Clearfil tri-S bond	K042913 (Kuraray Medical inc.)

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), DMG-USA has provided information to demonstrate conformity with FDA's guidance document entitled ***Guidance for Industry and FDA Staff: Dental Cements - Premarket Notification*** (August 1998) and ***Guidance for Industry and FDA Staff: Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions*** (October 2005).

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate devices, the Nanocomposite Restorative Kit has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2008

DMG USA, Incorporated
C/O Ms. Pamela Papineau
Regulatory Affairs Consultant
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K080480
Trade/Device Names: Nanocomposite Restorative Kit
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF and KLE
Dated: May 5, 2008
Received: May 12, 2008

Dear Ms. Papineau:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K080480

Device Name: **Nanocomposite Restorative Kit**

Product Indications for Use:

The Nanocomposite Restorative Kit consists of 2 types of nanocomposite restorative materials with a compatible bonding agent. The specific indications of each kit component are as follows:

1. **Nanocomposite** is indicated for:
- Restorations of all cavity classes
- Fabrication of direct inlays, onlays and indirect veneers
- Core build-up after tooth preparation with the root canal post
- Machinable Composite for Restorations
- Indirect Inlays/Onlays

2. **Nanocomposite Flowable** is indicated for:
- Small fillings of cavity classes III, IV and V
- Minimally invasive fillings for deciduous teeth (all cavity classes)
- Splinting of teeth

3. **MDP One Bottle Bond** is indicated for:
- Bonding resin-based materials (especially light-cure composite / compomer materials) to tooth structure (dentin and enamel)

Prescription Use X OR Over-the -Counter Use ____

(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080480