K093338

510(k) Summary

Trade Name: **Self adhesive composite luting cement**

Sponsor: DMG USA, Inc. FEB 12 2010
23 Frank Mossberg Drive
Attleboro, MA 02703
Registration # not yet assigned
Owner/Operator No. 9005969

Device Generic Name: Self adhesive composite luting cement

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

Product Description
Self adhesive composite luting cement is a universal, self adhesive, dual-curing composite luting cement.

Indications for Use:
The Self adhesive composite luting cement is indicated for the adhesive fixing of ceramic, composite and metal-based inlays, onlays, crowns, bridges and posts, screws, veneers and orthodontic appliances.

Device Description:
The Self adhesive composite luting cement is a dental cement that complies with the requirements set forth in the following standards:

- *ISO 7405:1997 Dentistry - Preclinical evaluation of biocompatibility of medical devices used in dentistry - Test methods for dental materials*
- *ISO 4049: 2000; Dentistry - Polymer-based Filling, Restorative and Luting materials*

Predicate Devices:
The components of the proposed Self adhesive composite luting cement are substantially equivalent to several currently marketed dental cements including the following:

Self adhesive composite luting cement:

Product Name	Predicates
Unicem	K062292 (3M ESPE AG)
Maxcem	K041474 (Sybron Dental Specialties, 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 Self adhesive composite luting cement has been shown to be safe and effective for its intended use.

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

FEB 12 2010

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

Re: K093338
Trade/Device Names: Self Adhesive Composite Luting Cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: January 22, 2010
Received: January 27, 2010

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. 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,

for

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

510(k) Number (if known): K093338

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Product Indications for Use:

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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)

Kevin Mulhy for MSR

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

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