AUG 3 0 2004

K041960

Attachment K
510(k) Summary

Trade Name: **Composite/Compomer Repair Kit**

Sponsor:
DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned
Owner/Operator No. 9005969

Device Generic Name: Dental restorative material and bonding agent

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

Predicate Devices:
The proposed DMG-USA Composite/CompomerKit restorative material is substantially equivalent to several currently marketed dental restorative materials:

Product Name	510(k) #	Manufacturer
PrimaFlow	K002086	DMG USA
Zenith Flowable Composite	K970683	Foremost Dental Mfg.
Composite Repair	K992879	DMG-Hamburg
Clearfill Repair	K001914	Kuraray Co., Ltd.
PermaCem	K012316	DMG USA
LuxaCore/uxaCore Dual	K012307	DMG USA
Solobond Plus	K003153	Voco
Tag Bong	K845033	Foremost Dental Mfg.
Xeno III	K023776	Dentsply
iBond	K022612	Heraeus Kulzer

Product Description/Indications for Use:
The **Composite/Compomer Repair Kit** consists of 4 materials:

1. A general 6th generation bonding agent for enamel and dentin,
2. A special bonding agent for resin-based materials in general, i. e. composites, compomers, and ormocers,
3. A flowable compomer and
4. A flowable composite

Bonding System is indicated for

- bonding chemically cured, light cured, or dual cured resin-based materials e. g. composite, compomer, ormocer materials to tooth structure (dentin and enamel)
- treatment of hypersensitive teeth

Composite Repair MMA-free is indicated

- as a bonding agent for the intraoral repair of poor or damaged resin-based materials composite restorations
- as a bonding agent for composite-based posts
- for shade corrections of esthetically unsatisfying restorations
- for repair and completion of temporary crowns and bridges
- as a bonding agent on resin-based materials

PrimaFlow is indicated for

- minimally invasive restorations
- Class III and V restorations
- bases
- extended fissure sealing
- restorations of all classes of cavities in deciduous teeth
- as a temporary luting cement for e.g. veneers, and
- as a flowable compomer repair agent .

Flowable Composite is indicated as

- as an aesthetic anterior restoration
- a base restoration under posterior or anterior composites
- an add-on or repair material for provisional crowns & bridges
- for incorporation of most mechanically anchored attachment components into the acrylic base of an overdenture or partial denture.
- as a temporary luting cement for e.g. veneers, and
- as a flowable composite repair agent .

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 Composites - Premarket Notification*** (November 1998).

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate devices, the Composite/Compomer Repair Kit restorative materials have 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

AUG 3 0 2004

Ms. Pamela Papineau, RAC
Consultant
DMG USA, Incorporated
414 South State Street
Dover, Delaware 19901

Re: K041960
Trade/Device Name: Composite/Compomer Repair Kit
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE and EBF
Dated: June 15, 2004
Received: July 21, 2004

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 (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner

for Chiu S. Lin, PhD
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): K041960

Device Name: Composite/Compomer Repair Kit

Indications for Use:

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2. a special bonding agent for resin-based materials in general, i. e. composites, compomers, and ormocers,
3. a flowable compomer and
4. a flowable composite

Bonding System (Contax) is indicated for

- bonding chemically cured, light cured, or dual cured resin-based materials e. g. composite, compomer, ormocer materials to tooth structure (dentin and enamel)
- treatment of hypersensitive teeth

Composite Repair MMA-free is indicated

- as a bonding agent for the intra- or extraoral repair of poor or damaged resin-based materials restorations
- as a bonding agent for composite-based posts
- for shade corrections of esthetically unsatisfying restorations
- for repair and completion of temporary crowns and bridges
- as a bonding agent on resin-based materials

PrimaFlow is indicated for

- minimally invasive restorations
- Class III and V restorations
- bases
- extended fissure sealing
- restorations of all classes of cavities in deciduous teeth
- as a temporary luting cement for e.g. veneers, and
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Flowable Composite (LuxaFlow) is indicated as

- as an aesthetic anterior restoration
- a base restoration under posterior or anterior composites
- an add-on or repair material for provisional crowns & bridges
- for incorporation of most mechanically anchored attachment components into the acrylic base of an overdenture or partial denture.
- as a temporary luting cement for e.g. veneers, and
- as a flowable composite repair agent .

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the -Counter Use ____ (21 CFR 807 Subpart D)

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

510(k) Number: K041960