SEP 1 8 2008

K081493

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510(k) Summary

Trade Name: **Infiltration Kit**

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

Device Generic Name: Infiltration Kit

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

Product Description:
The purposed Infiltration Kit consists of two components, a light curing resin-based sealant (Infiltrant) combined with a 99.5% ethanol solution, which is used in a drying and conditioning step before the sealant application and as second component an HCl-Etching-Gel. The HCl-Etching-Gel is used as a preliminary step for etching of enamel. The proposed sealant (Infiltrant) is designed for use in sealing the enamel pits and fissures of teeth.

Product Indications for Use:
The Sealant (Infiltrant) is indicated for:

- Sealing of Pit and Fissures
- Sealing/facing of damaged enamel surfaces
- Covering of caries predilection sites during orthodontic treatment
- Sealing of secondary teeth
- Sealing of deciduous teeth

The HCl Etching Gel is indicated for etching of enamel.

Predicate Devices:
The Infiltration Kit materials are substantially equivalent to several currently marketed dental restorative materials including the following:

Infiltrant:

Product Name	Predicates
3M Clinpro Sealant	K992326 (3M Company USA)
Admira Seal	K021842 (VOCO, GmbH)
Grandio Seal	K062344 (VOCO, GmbH)

HCl-Etching-Gel:

Product Name	Predicates
Enamel Microabrasion Compound	K891536 (Premier Dental Products USA, Co.)

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."

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Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate devices, the Infiltration 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

SEP 1 8 2008

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

Re: K081493
Trade/Device Name: Infiltration Kit
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Code: EBC
Dated: September 7, 2008
Received: September 11, 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.

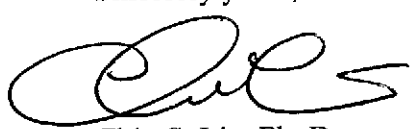
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

K081493

510(k) Number (if known): K081439

Device Name: **Infiltration Kit**

Product Indications for Use:

The Sealant (Infiltrant) is indicated for:

- Sealing of Pits and Fissures
- Sealing/facing of damaged enamel surfaces
- Covering of caries predilection sites during orthodontic treatment
- Sealing of secondary teeth
- Sealing of deciduous teeth

The HCl Etching Gel is indicated for etching of 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)

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

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