K100062

Section 5 – 510(k) Summary

Trade Name:	**Infiltration Kit**
Date Prepared:	March 12, 2010 MAR 2 6 2010
Sponsor:	DMG USA, Inc. 23 Frank Mossberg Drive Attleboro, MA 02703 David Sklarski 508-226-5660 Registration # not yet assigned Owner/Operator No. 9005969
Device Common/Usual Name:	Infiltration Kit
Classification/Regulation:	Sealant, Pit & Fissure, and Conditioner (21 CFR 872.3765; Class II)
Predicate Devices:	Infiltration Kit; K081439 (DMG USA, Inc.) SPK Sealant; K091632 (3M ESPE)

Product Description:
The DMG USA Infiltration Kit consists of two components, a light curing methacrylate 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. As preliminary step the HCl-Etching-Gel is used for etching of enamel. The Sealant (Infiltrant) is a low viscosity light-curing dental resin, which is a protective coating for tooth surfaces predisposed to caries or on early non-cavitated lesions. Other uses include sealing of pits and fissures, damaged enamel surfaces and exposed dentin surfaces of teeth to prevent caries.

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
- Sealing of pits and fissures, damaged enamel surfaces of teeth to prevent caries
- Protective coating for tooth surfaces predisposed to caries or on early non-cavitated lesions

HCl-Etching-Gel is indicated for:
- Etching of enamel

Substantial Equivalence
Substantial Equivalence for the DMG Infiltration Kit is based upon physical comparison to the predicate device; the Infiltration Kit described in this submission is identical to that cleared in K081493. This submission is for a labeling change to expand the indications for use statement for the Infiltration Kit cleared in K081439 to include two specific uses for the material: *Sealing of damaged enamel surfaces and exposed dentin surfaces of teeth to prevent caries* and *Protective coating for tooth surfaces predisposed to caries or on early non-cavitated lesions (including use in tooth brush abrasion and root surfaces).*

Technological Characteristics
The Infiltration Kit described in this submission is identical to the Infiltration Kit cleared in K081493. The chemical compositions of the Infiltration Kit materials are also equivalent to those of the 3M ESPE SPK Sealant, which was cleared in K091632 for the same indications for use proposed in this submission. Because the DMG USA Infiltration Kit and 3M ESPE SPK Sealant materials are so close in chemical

composition, the substantial equivalence testing provided in this submission is limited to viscosity and depth of cure for the two materials. The new and predicate materials are identical in terms of depth of cure; there is less than a 5% difference in viscosity between the DMG USA device and the predicate 3M ESPE device.

Conclusion:
Based on the indications for use, technological characteristics, and *in-vitro* test data contained in this submission, 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Pamela Papineau,
Regulatory Affairs Consultant
DMG USA, Incorporated
23 Frank Mossberg Drive
Attleboro, Massuchusetts 02703

MAR 2 6 2010

Re: K100062
Trade/Device Name: Infiltration Kit
Regulation Number: 21 CFR 872.3765
Regulation Name: Pit and Fissure Sealant and Conditioner
Regulatory Class: II
Product Codes: EBC
Dated: January 8, 2010
Received: January 15, 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): K100062

Device Name: **Infiltration Kit**

Product Indications for Use:

1. **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
- Sealing of damaged enamel surfaces and exposed dentin surfaces of teeth to prevent caries
- Protective coating for tooth surfaces predisposed to caries or on early non-cavitated lesions (including use in tooth brush abrasion and root surfaces)

2. **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)

RSBetz DDS for Dr. K.P. Mulay

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

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