K023649

510(k) Summary

JAN 17 2003

Trade Name: **Vitique System**

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned

Device Generic Name: Dental luting material

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

Predicate Devices:

Product Name	510(k) #	Manufacturer
Variolink II	K971372	Vivadent
Nexus	K972858	Kerr
Panavia F	Unknown	Kuraray
Calibra	Unknown	Dentsply
Rely X	K022476	3M
Vitremer	K933139	3M
Principle	Unknown	Dentsply
ProTec Cem	K980922	Vivadent

Product Description:
The Vitique System consists of:

- **Vitique Cement** - a highly aesthetic luting cement in various shades;
- **Try-In Pastes** - that precisely match the corresponding cement shade to approximate the final result;
- **Silanating agent** - for use in preparing ceramic surfaces for bonding; and
- **Contax Bonding System** - a bonding system (etching gel, bonding system) for final bonding to tooth structure.

Indications for Use:
The Vitique System is intended for use in permanent luting of definitive restorations of all kinds (metal, ceramic, composite), including veneers, crowns and bridges, onlays, telescopic crowns, attachments, pins and posts, orthodontic appliances, luting of ornaments, splinting etc. as well as a add-on for resin based materials. The Try-in pastes may also be used as a general water soluble separating agent (e.g. isolating material for use with prefabricated crowns, retraction cords etc.) or as an oxyguard gel.

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, Inc. has provided information to demonstrate conformity with FDA's guidance document entitled ***Dental Cements - Premarket Notification***, August 1998 and ISO 4049 – Dentistry – Polymer-based filling, restorative and luting materials.

Conclusion:
Based on their indications for use, technological characteristics, and comparison to predicate devices, the Vitique System materials have been shown to be safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

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

Re: K023649
Trade/Device Name: Vitique System
Regulation Number: 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: October 18, 2002
Received: October 30, 2002

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.

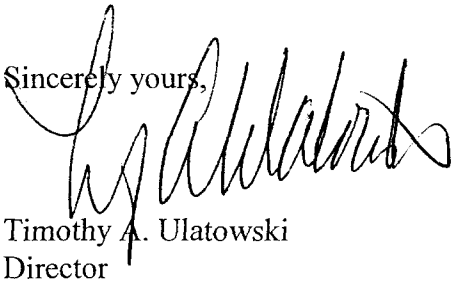
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



Timothy A. Ulatowski
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): K023649

Device Name: Vitique System

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Susan Runner

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

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