FEB 2 4 2004 K033996

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ..... 3M ESPE AG

Street: ..... ESPE Platz

ZIP-Code, City: ..... D-82229 Seefeld

Federal State: ..... Bavaria

Country: ..... Germany

Establishment Registration Number 9611385

Official Correspondent: ..... Dr. Andreas Petermann,
Manager U.S. Regulatory Affairs

Phone: 011-49-8152-700 1395

Fax: 011-49-8152-700 1869

E-mail: ..... Andreas.Petermann@mmm.com

Date: ..... December 22, 2003

Name of Device

Proprietary Name: ..... Hermes

Classification Name: ..... Tooth Shade Resin Material

Common Name: ..... Epoxy-Based Universal Restorative,
Resin-Based Filling Material

Predicate Devices

3M ESPE HAUR by 3M ESPE ..... K 010781

Tetric Ceram by Vivadent ..... K 964285

AH Plus by Dentsply ..... K 960548

Pertac II by ESPE ..... K 962440

Ketac Molar by ESPE ..... K 960954

Description for the Premarket Notification

Hermes is classified as Tooth Shade Resin Material because it is a device intended to restore carious lesions or structural defects in teeth. Tooth Shade Resin Material is designated at 21 C.F.R. § 872.3690 as a Class II device.

Hermes is a one component dental filling composite. Hermes uses different monomer chemistry and a different polymerization mechanism than most filling composites which are currently commercially available.

Based on its particular chemistry, Hermes reveals considerably low shrinkage properties. Thus, Hermes may lead to significant advantages in the dental office such as reduced stress to cavity walls. On the other hand, the clinician can fill the cavity in much larger increments (layers) in one step compared to methacrylate based composites leading to time savings and reduced stress for the patient.

Comparison to the predicate devices for performance data and indications for use shows that Hermes is substantially equivalent to the predicate devices.

Biocompatibility testing for Hermes provides evidence that the device is safe for its intended use.

In summary, it can be concluded that safety and effectiveness requirements for Hermes are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 4 2004

Dr. Andreas Petermann
Manager, U.S. Regulatory Affairs
3M ESPE AG
ESPE Platz
Seefeld, D-82229
GERMANY

Re: K033996
Trade/Device Name: Hermes
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Codes: EBF
Dated: December 22, 2003
Received: December 24, 2003

Dear Dr. Petermann:

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.

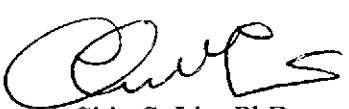
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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

Indications for Use

510(k) Number (if known): K033996

Device Name: Hermes

Indications For Use:

- Direct anterior restorations including:
  Class III, IV, V and VI
  Veneers
  Incisal edge repair
- Direct posterior restorations including:
  Class I or II or V
  Sandwich technique with glass ionomer resin material
  Cusp buildups
- Core buildups
- Splinting
- Indirect anterior and posterior restorations including:
  Inlays
  Onlays
  Veneers

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K033996