MAY 1 0 2004 K040857

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: ..... March 30, 2004

Name of Device

Proprietary Name: ..... Adper Prompt

Classification Name: ..... Resin Tooth Bond Agent

Common Name: ..... Dental Adhesive

Predicate Devices:

Adper Prompt by 3M ESPE ..... K 020946

Gluma Comfort Bond + Desensitizer ..... K 992292
by Heraeus Kulzer

Description for the Premarket Notification

Adper Prompt is classified as Resin Tooth Bond Agent (21 C.F.R. § 872.3200) because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials (compomer amd composite restorative material).

Additionally, as recent results show, Adper Prompt can be used to seal dentinal tubules of exposed dentin surfaces to prevent from dentinal hypersensitivity. 3M ESPE submits this 510(k) premarket notification to seek clearance for this new indication for use.

Performance and comparative testing of Adper Prompt has been carried out. The results suggest that Adper Prompt is a suitable agent to reduce fluid movement and to prevent from dentinal hypersensitivity.

The chemical composition of Adper Prompt remained unchanged in comparison to 510(k) K 020946. Performance data for Adper Prompt as a dental bonding agent are, therefore, not subject of this 510(k) submission.

The data provided in this 510(k) submission show that Adper Prompt is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 0 2004

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

Re: K040857
Trade/Device Name: Adper™ Prompt™
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE and EMA
Dated: March 30, 2004
Received: April 07, 2004

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.

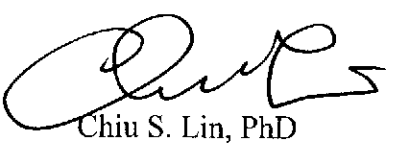
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K040857

Device Name: Adper Prompt, Adper Prompt L-Pop

Indications For Use: Bonding between dentin/enamel and composite filling materials
Bonding between dentin/enamel and compomer filling materials
Bonding mediator for fissure sealing
Desensitization of hypersensitive areas of teeth

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

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