K994251

JAN - 3 2000

IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ..... ESPE Dental AG

Street: ..... ESPE Platz

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

Federal State: ..... Bavaria

Country: ..... Germany

Establishment Registration Number: ... 9611385

Contact: ..... Dr. Andreas Petermann, Manager U.S. Regulatory Affairs

Phone: 011-49-8152-700 1395

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E-mail ..... Andreas_Petermann@ESPE.de

Date: ..... December 15, 1999

Name of Device

Proprietary Name: ..... KETAC®-MOLAR QUICK

Classification Name: ..... Dental cement

Common Name: ..... Glass ionomer cement

Predicate Device

KETAC®-MOLAR ..... K 960954

Description for the Premarket Notification

KETAC®-MOLAR QUICK is a dental glass ionomer cement (other than zinc oxide-eugenol) to serve e.g. as a temporary tooth filling and is classified according to 21 C.F.R. § 872.3275(b) as a class II device.

ESPE is submitting this Special 510(k) for modifications to its glass ionomer restorative cement KETAC®-MOLAR. The modified material is characterized by a

shorter setting time. The material will be marketed under the name KETAC®-MOLAR QUICK.

Like KETAC®-MOLAR, KETAC®-MOLAR QUICK is available in capsules tradenamed APLICAP®.

The modified glass ionomer cement KETAC®-MOLAR Quick has the following similarities to the unmodified KETAC®-MOLAR:

- KETAC®-MOLAR QUICK has the same intended use
- KETAC®-MOLAR QUICK is used by the same operating principle
- KETAC®-MOLAR QUICK incorporates the same basic chemical design
- KETAC®-MOLAR QUICK has the same shelf life
- KETAC®-MOLAR QUICK is manufactured and packaged using the same materials and processes

All chemical components of KETAC®-MOLAR QUICK are already part of the predicate device KETAC®-MOLAR, are contained in other 510(k) cleared devices manufactured by ESPE, or are described in a pharmacopoeia. Therefore, we believe that additional biocompatibility testing is not required.

In summary the modified KETAC®-MOLAR QUICK described in this 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 3 2000

Dr. Andreas Petermann
Manager U.S. Regulatory Affairs
ESPE Dental AG
ESPE Platz
D-82229 Seefeld, Bavaria
Germany

Re: K994251
Trade Name: KETAC®-Molar Quick
Regulatory Class: II
Product Code: EBF
Dated: December 15, 1999
Received: December 17, 1999

Dear Dr. Petermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K994251

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: K994251

Device Name: KETAC®-MOLAR QUICK

Indications for use:

Linings for class I and II cavities filled with composite

Core build-ups

Fillings in deciduous teeth

Fillings in class I cavities located in non-occlusal load bearing areas

Fillings in class V cavities if the esthetics are not of primary importance

Temporary fillings in class I and II cavities

Prescription use: ☑ Over-the counter use ☐

(Division Sign-Off) Pamela Scott for Susan Runner
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994251