OCT 7 1999

K992966

## II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Name: ..... 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 of U.S. Regulatory Affairs

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Date: ..... August 31, 1999

Name of Device

Proprietary Name: ..... REFERENCE®

Classification Name: ..... Tooth shade resin material

Common Name: ..... Composite restorative material

Predicate Devices

PERTAC® II by ESPE ..... K 962440

PROMPT® L-POP by ESPE ..... K 984246

HYTAC® by ESPE ..... K 962442

KETAC®-MOLAR by ESPE ..... K 960954

Description for the Premarket Notification

REFERENCE® is classified as a tooth shade resin material (21 C.F.R. § 872.3690) because it is a device composed of methacrylates intended to restore carious lesions or structural defects in teeth.

REFERENCE® is similar in intended use and substantially equivalent to ESPE's previously 510(k) cleared composite filling material PERTAC® II.

REFERENCE® is a further development based on the experience with PERTAC® II. The material characteristics were improved to obtain better handling and wearing properties. Furthermore, REFERENCE® is able to release fluoride ions. ESPE's glass ionomer filling material KETAC®-MOLAR is provided as a predicate fluoride releasing device, therefore.

All ingredients of REFERENCE® were used in PERTAC® II, except two chemical compounds which are, however, contained in ESPE's 510(k) cleared compomer bonding material PROMPT® L-POP® and in ESPE's 510(k) cleared compomer restorative material HYTAC®. In addition, biocompatibility tests were carried out to ensure the safety of REFERENCE®. The results show that REFERENCE® is a safe device with no harmful potential.

In particular, REFERENCE® has the following similarities to its predecessor PERTAC® II:

- REFERENCE® has in general the same intended use
- REFERENCE® is used by the same operating principles
- REFERENCE® incorporates the same basic chemical design
- REFERENCE® has the same shelf life
- REFERENCE® is manufactured using the same materials and processes

In summary, ESPE's new composite restorative material REFERENCE® described in this submission is, in our opinion, substantially equivalent to the predicate device.

The substantial equivalence to the well established PERTAC® II, the performance data and the results of biocompatibility testing provide evidence that safety and effectiveness requirements of REFERENCE® are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1999

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

Re: K992966
Trade Name: REFERENCE®
Regulatory Class: II
Product Code: EBF
Dated: August 31, 1999
Received: September 2, 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

K992766

## III. STATEMENT OF INDICATIONS FOR USE

Device Name: REFERENCE®

Indications for use: Composite restorative material for:

Restorations of type I, II, III, IV, and V cavities (according to Black)

Fillings in deciduous teeth

Extended fissure sealing

Cervical erosions and abrasions

Cutting edge build-up

Repairing of veneers made of composite and ceramics

Inlays fabrication

Interlocking of loose teeth

Prescription Use ✓
(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of [illegible] and General Hospital Devices
510(k) Number K992966