AUG 16 1999

K992048

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, Regulatory Affairs
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Date: ..... June 15, 1999

Name of Device

Proprietary Name:..... PROMPT® L-POP®
Classification Name: ..... Resin Tooth Bonding Agent
Common Name:..... Dental Adhesive

Predicate Device

PROMPT® L-POP® by ESPE ..... K 984246
(old formula)

Description for the Premarket Notification

PROMPT® L-POP® is classified as a Resin Tooth Bonding 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 and composite restorative material).

On January 8, 1999 a device called PROMPT® L-POP® was 510(k) cleared by the FDA (K 984246). The intended use of PROMPT® L-POP® (old formula) was limited to the bonding of compomer restorative materials. By little variations of the product

composition it is now possible to expand the range of indications on bonding of composite restorative materials as well.

Due to the FDA guidance document: "Deciding When to Submit a 510(k) for a Change to an Existing Device" published by the Office of Device Evaluation on January 10, 1997 a new 510(k) has to be submitted because labeling changes of PROMPT® L-POP® affect the indications for use.

However, PROMPT® L-POP® (new formula) is similar and substantially equivalent to PROMPT® L-POP® (old formula). To provide evidence for the safety of the device, the material safety data sheets of the components and a toxicological assessment carried out by an independent institute are attached. The effectiveness of PROMPT® L-POP® is established by performance data.

The results of safety and effectiveness analysis show that the range of indications of the device can be expanded and that PROMPT® L-POP® is a safe and effective dental adhesive.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 1999

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

Re: K992048
Trade Name: Modification of Prompt L-Pop
Regulatory Class: II
Product Code: KLE
Dated: June 15, 1999
Received: June 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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucente/for

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

Enclosure

K992048

STATEMENT OF INDICATIONS FOR USE

Device Name: 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

Bonding mediator for bracket attachment

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992048

Prescription use: ☒ Over-the counter use ☐