

K984246

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  
 Contact:..... Dr. Andreas Petermann, Regulatory Affairs  
 Phone:..... 011-49-8152-700395  
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 E-mail ..... Andreas\_Petermann@ESPE.de  
 Date:..... 11/17/1998

Name of Device

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

Predicate Devices

HYTAC® OSB by ESPE..... (K962442)  
 HYDROGUM® by Zhermack..... (K935898)  
 COMPOLUTE® by ESPE..... (K974458)

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 restorative material).

PROMPT® L-POP® is similar and substantially equivalent in intended use, composition, and function to ESPE'S compomer bonding material HYTAC® OSB. The filler of PROMPT® L-POP® is contained in Zhermack's alginate based impression material HYDROGUM®. ESPE's composite luting cement COMPOLUTE®

contains the same photo initiator. All above mentioned predicate devices are well established and determined to be safe and effective.



JAN 8 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K984246  
Trade Name: Prompt® L-Pop®  
Regulatory Class: II  
Product Code: KLE  
Dated: November 17, 1998  
Received: November 27, 1998

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.

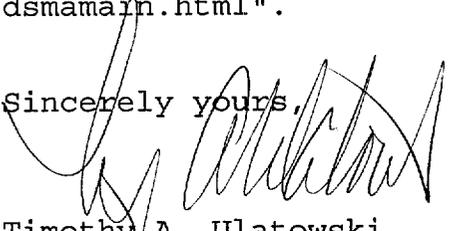
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



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

Enclosure

STATEMENT OF INDICATIONS FOR USE

Device Name:

PROMPT® L-POP®

Indications for use:

Bonding of Enamel/Dentin and Compomer  
Restorative Materials

*Susan Ruether*

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

510(k) Number

*K989246*

Prescription use:

Over-the counter use