

K974458

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

FEB - 2 1998

ESPE is submitting a 510(k) premarket notification for its composite luting cement, tradenamed Compolute® Aplicap®. Compolute® Aplicap® is indicated for the adhesive cementation of (all-porcelain-, composite-, and metal-) inlays, onlays, crowns, bridges, passive and threaded posts, and veneers. The product is composed of powder and liquid portions.

For composition, ESPE is claiming substantial equivalence to its previously cleared dental cement Sono®-Cem (K913966) and tooth shade resin material Pertac® II (K962440). The ingredients in ESPE's Compolute® Aplicap® are contained in Sono®-Cem and/or Pertac® II, with the exception of: (1) strontium aluminum lanthanum fluoro silicate glass, which is contained in ESPE's Ketac-Fil Aplicap Plus (K973262); and (2) pigment white 6 and phosphine oxide, which are contained in ESPE's Protemp® Garant temporary crown and bridge resin material (K950203).

For indications, ESPE is claiming substantial equivalence to its Sono®-Cem product, Kuraray Co. Ltd.'s Panavia® 21, Vivadent's Variolink II, 3M's Scotchbond Resin Cement, and Kerr's Nexus dental cements, all of which have substantially similar intended uses.

To support substantial equivalence to predicate products, the physical and technical characteristics of Compolute® Aplicap® have been compared to the listed predicates.

Compolute® Aplicap® meets the requirements of DIN, ISO and ADA standards for dental cements.

To support safe use of Compolute® Aplicap®, fluoride release data have been provided on the product.

ESPE's 510(k) has been submitted on November 25, 1997, by Dr. Barbara Wagner-Schuh at ESPE Platz, D-82229 Seefeld, Germany (011-49-8152-700395).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Dr. Barbara Wagner-Schuh  
Regulatory Affairs  
ESPE Dental-Medizin GmbH & Company, KG  
ESPE Plaza  
D-82229 Seefeld,  
Germany

Re: K974458  
Trade Name: Compolute® Aplicap®  
Regulatory Class: II  
Product Code: EMA  
Dated: January 29, 1998  
Received: January 29, 1998

Dear Dr. Wagner-Schuh:

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.

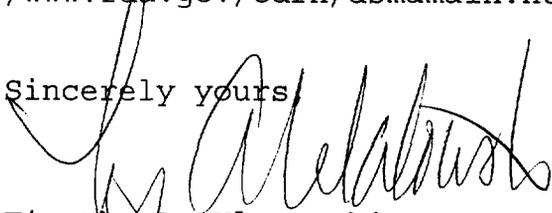
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4618. 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

**STATEMENT OF INDICATIONS FOR USE**

Device Name:            Comolute® Aplicap®

Indications for use:    Adhesive cementation of (all-porcelain-, composite-, and metal-) inlays, onlays, crowns, bridges, passive, and threaded posts and veneers

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K974458

Prescription Use X

OR

Over-The-Counter Use