

K973262

NOV 17 1997

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for its modified glass ionomer cement material, Ketac-Fil® Aplicap® *Plus*. Modifications have been made to the following ESPE 510(k)s for glass ionomer cement material: (1) Photac-Fil® Aplicap® (K925027); and (2) Ketac-Molar® Aplicap® (K960954), to create a slightly modified product with two new pigments. The reason for this modification is to provide the user of conventional glass ionomer cement products with additional cement shade options of better translucency and improved aesthetics. Ketac-Fil® Aplicap® *Plus* is a glass ionomer cement material indicated for the following uses: (1) fillings of Black Classes III and V cavities; (2) wedge-shaped defects; (3) fissure sealing; (4) small Black Class I cavities; (5) deciduous teeth; and (6) core build-ups.

ESPE is claiming substantial equivalence to its previously cleared Photac-Fil® Aplicap® and Ketac-Molar® Aplicap® products. Ketac-Fil® Aplicap® *Plus* and Photac-Fil® Aplicap® have substantially similar intended uses, and the ingredients of the powder portion of the products are similar, except for a slightly modified silicate glass, and the addition of two new pigments. Ketac-Fil® Aplicap® *Plus* and Ketac-Molar® Aplicap® have similar intended uses, and the liquid portion of the products are identical.

To support substantial equivalence to predicate products, the physical and technical characteristics of Ketac-Fil® Aplicap® *Plus* have been compared to those of Photac-Fil® Aplicap® and Ketac-Molar® Aplicap®. In addition, certain tests have been conducted on Ketac-Fil®

Aplicap® *Plus* to confirm safe use of the modified silicate glass and new pigments used.

Cytotoxicity, mutagenicity, eye irritation, skin irritation, sensitization, and acute oral toxicity tests have been conducted, and results are provided.

Ketac-Fil® Aplicap® *Plus* meets the requirements of relevant DIN and ISO standards for dental cement.

ESPE's 510(k) has been submitted on August 29, 1997 by Dr. Barbara Wagner-Schuh, at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Barbara Wagner-Schuh
Regulatory Affairs
ESPE GMBH & Company KG
AM Griesberg 2
Seefeld, OBB.,
Germany

NOV 17 1997

Re: K973262
Trade Name: Ketac-Fil® Aplicap® Plus
Regulatory Class: II
Product Code: EMA
Dated: November 7, 1997
Received: November 12, 1997

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.

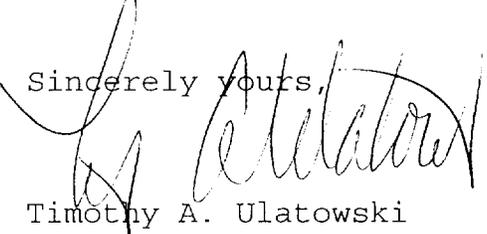
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

K 973262

Device Name: Ketac-Fil® Aplicap® Plus

Indications for use:

- Fillings of Black Classes III and V cavities
- Wedge-shaped defects
- Fissure sealing
- Small Black Class I cavities
- Deciduous teeth
- Core build-ups

Prescription Use X

OR

Over-The-Counter Use No

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

510(k) Number K973262