K972892

OCT - 2 1997

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for tooth shade resin material, tradenamed Cavit®-LC. Cavit®-LC is a light-curing temporary filling material indicated for the following uses: (1) temporary fillings for inlay and onlay preparations; (2) temporary fillings in cavities; (3) temporary fillings of implant sites; and (4) relining of prefabricated temporary crowns and bridges.

ESPE is claiming substantial equivalence to the previously cleared temporary filling materials Fermit-N Light-Curing Temporary Filling Material (K934978) and Clip® (K926418). Cavit®-LC, Fermit-N, and Clip® have similar intended uses and Cavit®-LC and Fermit-N have similar principal ingredient composition. To support substantial equivalence to predicate products, the physical and technical characteristics of Cavit®-LC have been compared to those of Fermit-N and Clip.® In addition, certain tests have been undertaken on the final Cavit®-LC product, including cytotoxicity, Ames, skin irritation, eye irritation, acute oral toxicity, and sensitization.

ESPE's 510(k) has been submitted on August 4, 1997, by Dr. Barbara Wagner-Schuh at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT - 2 1997

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

Re: K972892
Trade Name: Cavit-LC
Regulatory Class: II
Product Code: EBF
Dated: August 4, 1997
Received: August 5, 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

Device Name: Cavit®-LC

Indications for use:

- Temporary fillings for inlay and onlay preparations
- Temporary fillings of cavities
- Temporary filling of implant sites
- Relining of prefabricated temporary crowns and bridges

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K972849

Prescription Use X OR **Over-The-Counter Use** __