4/23/99

K990982

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
Phone: 011-49-8152-7001395
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E-mail . ..... Andreas_Petermann@ESPE.de
Date: ... . March 22, 1999

Name of Device

Proprietary Name: ..... CAVIT® LC
Classification Name: ..... Tooth shade resin material
Common Name: ..... Temporary light cured filling material

Predicate Device

CAVIT®-LC (old formula) by ESPE ..... K 972892

Description for the Premarket Notification

CAVIT® LC is classified as a tooth shade resin material (21 C.F.R. § 872.3690) because it is a device composed of methacrylates intended to restore carious lesions or structural defects in teeth.

CAVIT® LC is similar in intended use and substantially equivalent to ESPE's previously 510(k)-cleared temporary filling material CAVIT®-LC (old formula) which was never on the market because it was determined by consultant dentists to have very insufficient material characteristics. The consultants complained about too high rigidity of the uncured material which made it almost impossible to fill it into the cavity.

The new CAVIT® LC is a further development based on the experience with the old CAVIT®-LC. The composition has changed, especially the monomer system was exchanged, which results in more advantageous material and handling characteristics.

To support the safety of the new formulation, biocompatibility testing was conducted which showed that CAVIT® LC has no harmful potential. The effectiveness is established by laboratory testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 23 1999

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

Re: K990982
Trade Name: Cavit LC
Regulatory Class: II
Product Code: EBF
Dated: March 22, 1999
Received: March 24, 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,

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

Enclosure

K990982

STATEMENT OF INDICATIONS FOR USE

Device Name: CAVIT® LC

Indications for use:

Temporary fillings

Temporary management of inlay and onlay preparations

Temporary closure of implant screw holes

Relining of temporary pre-made crowns and bridges

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K990982

Prescription use: ☒ Over-the counter use ☐