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II. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for modifications to its 510(k) submission for polyvinyl siloxane impression material, tradenamed Dimension® Penta (K960547), now called Dimension® Penta H.[1/] The modifications have been made to create slightly modified impression materials, referred to by the tradenames Position® Penta and Position® Penta Quick. Position® Penta and Position® Penta Quick are indicated for use for impressions for temporary restorations, preliminary impressions, opposing dentitians and orthodontic models.

ESPE is claiming substantial equivalence to its previously cleared impression material, Dimension® Penta H. Position® Penta, Position® Penta Quick and Dimension® Penta H have the same basic intended use: taking impressions in the mouth. All three products are intended for use with an electronic mixing apparatus (Pentamix®) to be used table-side. Position® Penta, Position® Penta Quick and Dimension® Penta H are all composed of a base paste and catalyst. Position® Penta, Position® Penta Quick and Dimension® Penta H have the same catalyst composition except for use of a pigment identified as an alternative in the Dimension® Penta 510(k). The base paste composition of the products are similar, with the exception of:

1/ When ESPE's 510(k) was filed and cleared, the product was tradenamed Dimension® Penta. Subsequent to that time, the product name was changed to Dimension® Penta H to indicate "high consistency." At the time the 510(k) for Dimension® Penta was cleared, ESPE did not offer a low consistency version of the product, as it does now (Dimension® Penta L).

(1) variations of ingredient amounts; (2) use in Position® Penta and Position® Penta Quick of a new form/chemical structure of a previously used ingredient (silyl polyethylene oxides); and (3) use of new pigments identified as alternatives in the Dimension® Penta 510(k). To support substantial equivalence to the predicate product, the physical and technical characteristics of Position® Penta and Position® Penta Quick have been compared to those of Dimension® Penta H. Position® Penta and Position® Penta Quick meet the requirements of relevant DIN, ISO and ADA standards for impression material.

Biocompatibility tests, including cytotoxicity, AMES, skin irritation, eye irritation, acute oral toxicity, and sensitization, have been undertaken on the new form of ingredient (i.e., differing in chemical structure) used in the Position® Penta and Position® Penta Quick base paste, and also on final ESPE products containing that ingredient.

ESPE's 510(k) has been submitted on November 12, 1997, by Dr. Barbara Wagner-Schuh at ESPE Platz, 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 20850

JAN 29 1998

Dr. Barbara Wagner-Schuh
Regulatory Affairs
ESPE Dental-Medizin GmbH & Company KG
AM Griesberg 2
Seefeld, OBB.,
GERMANY

Re: K974231
Trade Name: Position Penta, Position Penta, Quick
Regulatory Class: II
Product Code: ELW
Dated: November 4, 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

Device Name: Position® Penta
Position® Penta Quick

Indications for Use:

- Impressions for temporary restorations
- Preliminary impressions (all types)
- Impressions of opposing jaws
- Impressions for orthodontic models

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974231

Prescription Use X or Over-the Counter Use _____