JUN 18 1999

K991068

## 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 24, 1999

Name of Device

Proprietary Name: ..... DIMENSION® BITE
Classification Name: ..... Impression material
Common Name: ..... Bite registration material

Predicate Devices

PANASIL® by Roydent ..... K 954281
DIMENSION® PENTA by ESPE ..... K 960547
PERMADYNE® GARANT® by ESPE ..... K 953374

Description for the Premarket Notification

DIMENSION® BITE is classified as an impression material (21 C.F.R. § 872.3660) because it is a device intended to reproduce the structure of a patient's teeth.

DIMENSION® BITE is similar in intended use and substantially equivalent to Roydent's polyvinyl siloxane based impression and bite registration material PANASIL® and ESPE's polyvinyl siloxane based impression material DIMENSION® PENTA.

In recent years ESPE was already marketing a bite registration material tradenamed DIMENSION® BITE in USA. This material is a private label product and

manufactured by Kettenbach. The same device is marketed in USA under the name FUTAR® OCCLUSION by Roydent. Roydent holds the 510(k) for the material (K 954281). To be independent from suppliers, ESPE decided to develop an own polyvinyl siloxane based bite registration material which will replace the private label material.

The basis for ESPE's new development is the good experience with its addition type silicone based impression material DIMENSION® PENTA.

The physical and mechanical properties of the new DIMENSION® BITE have been compared to those of the old DIMENSION® BITE (FUTAR® OCCLUSION).

The composition of the new DIMENSION® BITE contains the same ingredients as ESPE's DIMENSION® PENTA® impression material except one softening agent which is contained in ESPE's polyether based impression material PERMADYNE® GARANT®.

The above mentioned impression and bite registration materials are well established and considered to be safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 18 1999

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

Re: K991008
Trade Name: DIMENSION® BRITE
Regulatory Class: II
Product Code: ELW
Dated: March 24, 1999
Received: March 26, 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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

## III. STATEMENT OF INDICATIONS FOR USE

Device Name: DIMENSION® BITE

Indications for use: Bite registration

Intraoral guide pin excursion tracing

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K971064