

K991221

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
 Fax: 011-49-8152-7001869
 E-mail: Andreas_Petermann@ESPE.de
 Date: April 8, 1999

Name of Device

Proprietary Name: VESTOGUM®
 Classification Name: Impression Material
 Common Name: Gingiva Modeling Material

Predicate Device

IMPREGUM® PENTA by ESPE K 954192
 PERMADYNE® PENTA H by ESPE K 953027

Description for the Premarket Notification

VESTOGUM® is classified as a dental impression material (21 C.F.R. § 872.3660) because it is a device intended to be one step in the process to reproduce the structure of a patient's gums.

VESTOGUM® serves for making a gingiva model. Because of exposing the preparation border on the master cast, there is an essential lack of information with regard to the impressed soft tissues.

The gingiva modeling material on polyether basis, in color adapted to the natural gingiva, is a controlling material in order to avoid a displacement of the marginal

periodontium due to overcontoured crowns. VESTOGUM[®] thus contributes considerably to a periodontally hygienic functional and esthetic prosthesis.

VESTOGUM[®] consists of the same ingredients as IMPREGUM[®] PENTA, ESPE's proven and well-established polyether based impression material except one pigment. This pigment, however, is contained in ESPE's polyether based impression material PERMADYNE[®] PENTA H. The fact that no new ingredients are contained ensures in our opinion that no new toxicology and biocompatibility studies are necessary.

ESPE has long marketing experience with polyether based impression materials. IMPREGUM[®] F, which is the hand-mixed version of IMPREGUM[®] PENTA is marketed in the U.S.A. since 1986, the hand-mixed PERMADYNE[®] impression materials since 1980. In European countries, VESTOGUM[®] is successfully marketed for more than 10 years. In our opinion the marketing experience with VESTOGUM[®], the substantial equivalence of VESTOGUM[®] to the predicate devices IMPREGUM[®] and PERMADYNE[®] with long marketing history and clinical experience, and the performance data support the safety and effectiveness of VESTOGUM[®] for the intended use.



MAY 20 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991221
Trade Name: VESTOGUM®
Regulatory Class: II
Product Code: ELW
Dated: April 8, 1999
Received: April 12, 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 (Pre-market 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.

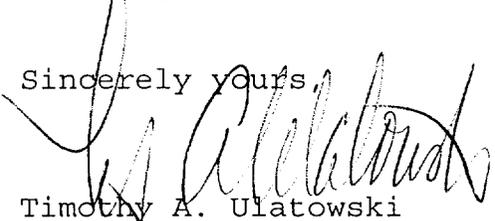
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws 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

K991221

STATEMENT OF INDICATIONS FOR USE

Device Name:

VESTOGUM®

Indications for use:

Gingiva Modeling Material for:

Combination works

when choosing and mounting the attachment,
the papilla is fully preserved

Telescopic works

the shoulder of the crowns to be cut is indicated
according to the gingiva contour

Anterior tooth area

with regard to esthetics and periodontal
hygienics, the forming possibilities of the
interdental spaces are increased

Forming of different tooth lengths

according to the natural conditions in the
patient's mouth, they can be adapted in
anatomically correct way; especially in bridge
spans

Color rating of the veneer material

the material which is in color adapted to the
gingiva, serves for more precise color matching

Controlled modellation

the cervical-incisal crown convexity for the
protection of the gingival margin can be
controlled

Prescription use:

Susan Puro

Over-the counter use

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K991221