

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  
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 E-mail ..... Andreas\_Petermann@ESPE.de  
 Date: ..... April 9, 1999

Name of Device

Proprietary Name: ..... VITRON® H  
 Classification Name: ..... Denture relining, repairing, or rebasing resin  
 Common Name: ..... Denture base material

Predicate Devices

PALADON® 65 by Kulzer ..... K 901789  
 PALAPRESS® VARIO by Kulzer ..... K 902115  
 LIQCRYLIC® by Dentsply ..... K 972573

Description for the Premarket Notification

VITRON® H is classified as a denture relining, repairing, or rebasing resin (21 C.F.R. § 872.3760) because it is a device composed of methylmethacrylate intended to be used in the fabrication of complete or partial removable dentures and other removable dental appliances.

VITRON® H is a pourable, heat cured material for the production of dentures according to the plugging-pressing procedure of flask polymerization. It is thus similar and substantially equivalent in intended use and function to Kulzer's denture relining, repairing, or rebasing resin PALADON® 65 (K 901789).

Though the composition of PALADON® 65 is not available it is known that it consists of the same common monomer system. Kulzer's PALAPRESS® VARIO and Dentsply's LIQCRYLIC® PRO DENTAL RESIN do also comprise similar monomers and use the same well-known barbituric acid catalyzed starting mechanism as VITRON® H.

Kulzer's PALADON® 65, PALAPRESS® VARIO and Dentsply's LIQCRYLIC® PRO DENTAL RESIN are well established and determined to be safe and effective devices.

PALAPRESS® VARIO is marketed in the United States since 1992. Dentsply has marketed the same device as SELECTA-PLUS® and TREVAPRESS® in Europe and South America for over 25 years. The technology of methyl methacrylate based denture base materials which are cured by a barbituric acid based catalyst system is over 30 years old and has a long clinical history. In our opinion biocompatibility studies are therefore not necessary to prove the safety and efficacy of VITRON® H's formulation.

In our opinion the substantial equivalence of VITRON® H to the predicate devices PALADON® 65, PALAPRESS® VARIO and LIQCRYLIC® PRO DENTAL RESIN with long marketing history and clinical experience, and the performance data support the safety and effectiveness of VITRON® H 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: K991220  
Trade Name: Vitron®H  
Regulatory Class: II  
Product Code: EBI  
Dated: April 9, 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.

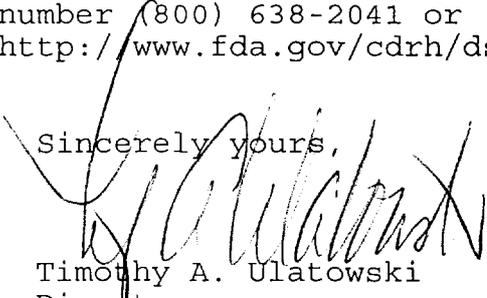
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Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws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

K991220

STATEMENT OF INDICATIONS FOR USE

Device Name: VITRON® H

Indications for use: Fabrication of full and partial dentures

Prescription use:

Over-the counter use

*Susan Rynn*

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(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K991220