

K992645

SEP 22 1999

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,  
 Manager U.S. Regulatory Affairs

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Date: ..... August 3, 1999

Name of Device

Proprietary Name: ..... SINFONY®

Classification Name: ..... Tooth shade resin material

Common Name: ..... Crown and bridge veneering composite  
 material

Predicate Device

SINFONY® (old version) by ESPE ..... K 973513

TARGIS® system by IVOCLAR ..... K 962878

FIBREKOR® by JENERIC/PENTRON.... K 964578

PERTAC® II by ESPE ..... K 962440

PROTEMP® GARANT by ESPE..... K 950203

VITRON® M by ESPE..... K 990763

VITRON® H by ESPE ..... K 991220

Description for the Premarket Notification

SINFONY® is classified as a tooth shade resin material (21 C.F.R. § 872.3690) because it is a device composed of methacrylates intended to be used for full and partial coverage of crowns and bridges and as a material for the fabrication of inlays and onlays to restore carious lesions or structural defects in teeth.

On December 22, 1997 SINFONY® as a veneering material for full and partial coverage of bridges and crowns received 510(k) clearance. As a demand of customers, the range of indications will now be expanded on material for fabrication of complete crowns, inlays and onlays and fiber reinforced crowns and bridges.

Pursuant to the 510(k) Memorandum #K97-1, released on January 10, 1997, "Deciding when to submit a 510(k) for a change to an existing device", the changes of SINFONY® affect the labeling and the indications for use and require, therefore, the submission of a new 510(k).

To give evidence that SINFONY® is capable for the new indications, performance test data are provided and compared to the predicate devices PERTAC® II (K 962440) TARGIS® system (K 962878), FIBREKOR® (K 964578) and PROTEMP® GARANT (K 950203), which are released as materials for the fabrication of inlays and onlays, crowns and fiber reinforced bridges respective. The comparison shows that SINFONY® is as effective as the predicate devices which are all well established on the world market.

The composition of SINFONY® was only changed slightly, a photo stabilizer has been added to some particular materials. This photo stabilizer is a well-known compound and also contained in some other already 510(k)-cleared ESPE products (VITRON® M, K 990763, VITRON® H, K 991220, PROTEMP® GARANT, K 950203). Therefore a new toxicological assessment is not required in our point of view.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Dr. Andreas Petermann  
Manager U.S. Regulatory Affairs  
ESPE Dental AG  
ESPE Plaza  
D-82229 Seefeld, Bavaria  
Germany

Re: K992645  
Trade Name: Sinfony®  
Regulatory Class: II  
Product Code: EBF  
Dated: August 3, 1999  
Received: August 6, 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. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

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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) 594-4690. 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

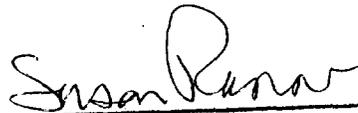
K992645

III. STATEMENT OF INDICATIONS FOR USE

Device Name: SINFONY®

Indications for use:

- Full veneering of crowns and bridges
- Complete crowns
- Inlays/onlays
- Fiber reinforced crowns and bridges
- Direct bonded bridges
- Telescopic and conical crowns
- Attachments and implant works
- Veneers
- Long term temporary restorations and their characterization
- Customization of acrylic and ceramic artificial teeth
- Extraoral repairs



(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K9 2645

Prescription Use   
(Per 21 CFR 801.109)