

NOV 24 1999

12992909

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

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Federal State: Bavaria
Country: Germany
Establishment Registration Number: ... 9611385
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Regulatory Affairs
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Date: August 27, 1999

Name of Device

Proprietary Name: HYTAC®
Classification Name: Tooth shade resin material
Common Name: Compomer filling material

Predicate Device

HYTAC® by ESPE..... K 962442
DYRACT® AP by DENTSPLY..... K 973235

Description for the Premarket Notification

HYTAC® is classified as a tooth shade resin material (21 C.F.R. § 872.3690) because it is a device composed of methacrylates intended to restore carious lesions or structural defects in teeth.

On September 11, 1996 HYTAC[®] was 510(k)-cleared by the FDA. Because at that time no further clinical evidence was available, the range of indications was strictly limited to none-occlusal loaded fillings. Therefore, the information for use contained a contraindication phrase “HYTAC[®] is not indicated [...] for long-term fillings in the permanent dentition exposed to occlusal loading”.

However, good clinical experience, laboratory test data and comparison to DYRACT[®] AP by a study make it now possible in our point of view to expand the range of indications to occlusal loaded fillings, too. The above mentioned contraindication phrase will therefore be deleted in the Instructions for Use. The range of indications for HYTAC[®] will be expanded on permanent class I fillings and semipermanent class II fillings. The phrase “semipermanent” has to be understood as a period of up to two years.

Due 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”, deletion of a contraindication on one hand and expanding the range of indications on the other hand requires the submission of a new 510(k).

While the composition of HYTAC[®] remains still the same, in this 510(k) submission only the differences to the old submission are cited. Therefore, no chemical and toxicological data is contained to reduce unnecessary paperwork.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K992909
Trade Name: Hytac®
Regulatory Class: II
Product Code: EBF
Dated: August 27, 1999
Received: August 30, 1999

Dear Dr. Andreas 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.

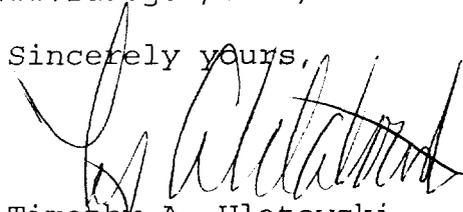
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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

STATEMENT OF INDICATIONS FOR USE

(As Required by 21 C.F.R. § 801.109)

510(k) Number: _____

Device Name: HYTAC®

Indications for use:

- Primary tooth fillings
- Class I, III, and V fillings
- Wedge-shaped defects
- Class II semipermanent fillings

Prescription use:

Over-the counter use



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number 2992909