

# 510(k) SUMMARY

**DENTSPLY**

NAME & ADDRESS:

**DENTSPLY International**  
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JAN 13 1999

K9843 87

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: December 3, 1998

TRADE OR PROPRIETARY NAME: R-30 AESTHETIC RESTORATIVE

COMMON OR USUAL NAME: Dental restorative material

CLASSIFICATION NAME: Tooth resin shade material

PREDICATE DEVICE: SureFil™ High Density Posterior Restorative K973221

**DEVICE DESCRIPTION:** R-30 AESTHETIC RESTORATIVE is a visible light activated, radiopaque restorative material for anterior and posterior restorations of primary and permanent teeth. It is to be used with Prime & Bond® NT™ Dental Adhesive System. The material is a one-component, VLC composite restorative, packaged in syringes or compules.

The physical properties of R-30 AESTHETIC RESTORATIVE meet ISO Standard 4049.

**INTENDED USE:** R-30 AESTHETIC RESTORATIVE is to be used with Prime & Bond® NT™ Dental Adhesive System for cavity classes I, II, III, IV, V and VI in anterior and posterior teeth as a direct restorative material, anterior direct veneering material, and may be used for the fabrication of indirect inlays and onlays.

**TECHNOLOGICAL CHARACTERISTICS:** The new R-30 AESTHETIC RESTORATIVE is substantially equivalent to the predicate device, K973221 (SureFil™ High Density Posterior Restorative).

We believe that the prior use of the R-30 AESTHETIC RESTORATIVE components in the predicate device supports our decision that additional biocompatibility studies with the final formulation are not necessary.

The results of Ames testing on the main components were negative.

We believe that the prior use of the components in the R-30 AESTHETIC RESTORATIVE in the predicate device, the performance data provided, and the results of previous biocompatibility testing support the safety and effectiveness of R-30 AESTHETIC RESTORATIVE for the intended uses.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. P. Jeffrey Lehn  
Director, Corporate Compliance  
and Regulatory Affairs  
DENTSPLY International  
570 West College Avenue  
P.O. Box 872  
York, Pennsylvania 17405-0872

Re: K984387  
Trade Name: R-30 Aesthetic Restorative  
Regulatory Class: II  
Product Code: EBF  
Dated: December 3, 1998  
Received: December 8, 1998

Dear Mr. Lehn:

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.

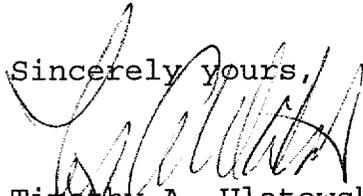
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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

K984387

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(K) Number: K984387

Device Name: R-30 AESTHETIC RESTORATIVE

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

Susan Purse

(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K984387

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