

510(k) SUMMARY

K 974140

DENTSPLY

NAME & ADDRESS:

JAN - 5 1998

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
Fax (717) 854-2343

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: October 31, 1997

TRADE OR PROPRIETARY NAME: ADHESIVE HYBRID IONOMER CEMENT

CLASSIFICATION NAME: Dental Cement 872.3275

PREDICATE DEVICE: Advance® Hybrid Ionomer Cement K940914

DEVICE DESCRIPTION: ADHESIVE HYBRID IONOMER CEMENT is a two-component, dual-cure, high-strength hybrid ionomer dental cement used for permanent cementation of crowns and bridges, and for adhesive bonding of fresh direct amalgam to tooth structure.

The cured product demonstrates adhesion to dentin and enamel, releases fluoride, and has suitable physical properties required for a dental luting cement, as well as a protective barrier.

The physical properties of ADHESIVE HYBRID IONOMER CEMENT are comparable to Advance® Hybrid Ionomer Cement (K940914).

INTENDED USE: ADHESIVE HYBRID IONOMER CEMENT is used for adhesive cementation of: all metal crowns and bridges including precious, semi-precious and non-precious metals, conventional porcelain fused to metal crowns and bridges with metal margins, gold inlays and onlays, prefabricated and cast posts, porcelain/ceramic/composite substrate crowns, porcelain jacket crowns (including foil or electroplated lined crowns), porcelain fused to metal crowns with porcelain margins; and as an adhesive liner for bonding freshly placed direct amalgam restorations.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in ADHESIVE HYBRID IONOMER CEMENT have either been used in legally marketed devices or have been found safe for dental use.

ADHESIVE HYBRID IONOMER CEMENT (cured material) was tested by the MEM Elution Test and the Ames Mutagenicity Test, and found to be non-cytotoxic and non-mutagenic. A histopathologic study of the effects of the product cured in the teeth of sub-human primates was conducted. All responses were found to be acceptable.

We believe that the prior use of the components of ADHESIVE HYBRID IONOMER CEMENT in legally marketed devices, the performance data, and the results of biocompatibility testing support the safety and effectiveness of ADHESIVE HYBRID IONOMER CEMENT for the intended uses.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 1998

Mr. Jeffery P. Lehn
Director of Corporate Compliance and Regulatory Affairs
DENTSPLY International
570 West College Avenue
York, Pennsylvania 17405

Re: K974140
Trade Name: Adhesive Hybrid Ionomer Cement
Regulatory Class: II
Product Code: EMA
Dated: October 31, 1997
Received: November 3, 1997

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 (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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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

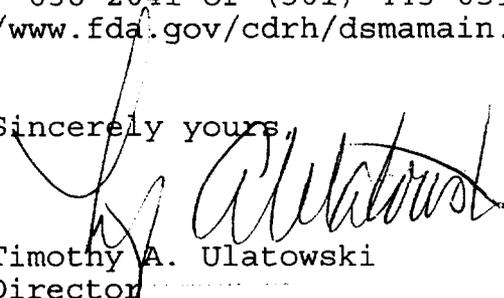
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4618. 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

PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 801.109)

510(K) Number: K974140

Device Name: ADHESIVE HYBRID IONOMER CEMENT

ADHESIVE HYBRID IONOMER CEMENT is used for:

- Adhesive cementation of all metal crowns and bridges including precious, semi-precious and non-precious metals
- Adhesive cementation of conventional porcelain fused to metal crowns and bridges with metal margins
- Adhesive cementation of gold inlays and onlays
- Adhesive cementation of prefabricated and cast posts.
- Adhesive cementation of porcelain/ceramic/composite substrate crowns
- Adhesive cementation of porcelain jacket crowns (including foil or electroplated lined crowns)
- Adhesive cementation of porcelain fused to metal (PFM) crowns with porcelain margins
- Adhesive liner for bonding freshly placed direct amalgam restorations

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off) *P.D. Scott for Susan Rimmer*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K974140

Prescription Use OR Over-The-Counter Use

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