510(k) SUMMARY

FEB - 5 1998

DENTSPLY

NAME & ADDRESS:

K973235

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
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P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED: August 27, 1997

TRADE OR PROPRIETARY NAME: DYRACT® AP RESTORATIVE

CLASSIFICATION NAME: Tooth resin shade material 872.3690

PREDICATE DEVICE: DYRACT® II Restorative K950991

DEVICE DESCRIPTION: DYRACT® AP RESTORATIVE is a one-component, visible light curing, dental restorative material, delivered in COMPULES®, which hardens upon polymerization. The composition is polymerized by brief exposure to visible light from a dental curing light. When polymerization occurs, the monomers cross-link to form polymer-containing carboxyl groups which are capable of further reaction with cations eluted from the glass-reinforcing filler to form a salt, as in DYRACT® II Restorative (K950991). The modifications to the DYRACT II Restorative serve to enhance the strength and wear resistance of DYRACT AP RESTORATIVE.

The physical properties of DYRACT AP RESTORATIVE and the predicate device are similar.

INTENDED USE: DYRACT AP RESTORATIVE is used as a permanent restorative material in all cavity classes for both permanent and deciduous teeth; as a base material underneath amalgams, ceramics, cast metal restorations, and composites; as a laminate or open sandwich technique; for root caries lesions; and for core build-up.

TECHNOLOGICAL CHARACTERISTICS: All components in DYRACT AP RESTORATIVE have been used in legally marketed devices or found to be safe for dental use.

DYRACT AP RESTORATIVE (cured material) was tested by the Ames Mutagenicity Test and Guinea Pig Sensitization Test. The cured material is non-mutagenic and a non-sensitizer.

We believe that the prior use of the components of DYRACT AP RESTORATIVE in legally marketed predicate devices, the results of the toxicity and sensitization testing, and the performance data support the safety and effectiveness of DYRACT AP RESTORATIVE for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 1998

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

Re: K973235
Trade Name: DYRACT® AP RESTORATIVE
Regulatory Class: II
Product Code: EBF
Dated: January 28, 1998
Received: January 30, 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 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

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: K973235

Device Name: DYRACT® AP RESTORATIVE

Indications for Use:

Used as a permanent restorative material in all cavity classes for both permanent and deciduous teeth; as a base material underneath amalgams, ceramics, cast metal restorations, and composites; as a laminate or open sandwich technique; for root caries lesions; and for core build-up

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(K) Number K973235

Prescription Use Yes OR Over-The-Counter Use No