

AUG 18 1998

K982395

510(k) SUMMARY



NAME & ADDRESS:

**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: JUL 08 1998

TRADE OR PROPRIETARY NAME: DYRACT® FLOW RESTORATIVE

COMMON OR USUAL NAME: Dental restorative material

CLASSIFICATION NAME: Tooth shade resin material 872.3690

PREDICATE DEVICE: Dyract® AP™ Restorative K973235  
Aeliteflo Composite K955292

DEVICE DESCRIPTION: DYRACT® FLOW RESTORATIVE is a one-component, moderately filled, visible light cured dental composite restorative material.

DYRACT® FLOW RESTORATIVE is a low viscosity, esthetic material for use as a composite restorative. It is a moderately filled, radiopaque, fluoride-releasing composite, primarily designed for restoration of shallow defects such as incipient Class V lesions.

The physical properties of DYRACT® FLOW RESTORATIVE meet ISO Standard 4049.

INTENDED USE: DYRACT® FLOW RESTORATIVE is used for: Filling of defects and undercuts in crowns, inlays and onlays; Liner under direct restorative materials and under inlay restorations—Class II box liner; Tunnel preparations; Pit and fissure sealants; Amalgam margin repair; Improving margins of acrylic temporaries; Small class IV repairs; Intraoral porcelain repair; Cementing porcelain veneers, crowns, inlays/onlays; Refacing acrylic temporaries; Blockouts; Covering incisal edge stains; Repair of small enamel defects; Provisional occlusal changes; Class III, V restorations; Conservative Class I restorations; and Margin correction/adjustment of composite crowns for indirect laboratory use.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in DYRACT® FLOW RESTORATIVE have either been used in predicate dental devices or have been found safe for dental use.

We believe that the prior use of the components of DYRACT® FLOW RESTORATIVE in legally marketed predicate devices, the performance data, and the biocompatibility data provided support the safety and effectiveness of DYRACT® FLOW RESTORATIVE for the indicated uses.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 18 1998

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: K982395  
Trade Name: Dyract® Flow Restorative  
Regulatory Class: II  
Product Code: EBF  
Dated: July 8, 1998  
Received: July 9, 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.

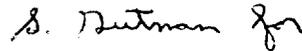
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

**PREMARKET NOTIFICATION**

**INDICATIONS FOR USE STATEMENT**

(As Required by 21 CFR 801.109)

510(K) Number: K982395

Device Name: DYRACT® FLOW RESTORATIVE

- Filling of defects and undercuts in crowns, inlays and onlays;
- Liner under direct restorative materials and under inlay restorations--Class II box liner;
- Tunnel preparations;
- Pit and fissure sealants;
- Amalgam margin repair; Improving margins of acrylic temporaries;
- Small class IV repairs;
- Intraoral porcelain repair;
- Cementing porcelain veneers, crowns, inlays/onlays;
- Refacing acrylic temporaries;
- Blockouts;
- Covering incisal edge stains;
- Repair of small enamel defects;
- Provisional occlusal changes;
- Class III, V restorations;
- Conservative Class I restorations;
- Margin correction/adjustment of composite crowns for indirect laboratory use

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter Use



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

510(k) Number K982395

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