JUL 10 1998

510(k) SUMMARY

DENTSPLY

NAME & ADDRESS:

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

K981965

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: June 3,1998

TRADE OR PROPRIETARY NAME: FLOWABLE COMPOSITE

COMMON OR USUAL NAME: Dental restorative material

CLASSIFICATION NAME: Tooth shade resin material 872.3690

PREDICATE DEVICE: Enforce® with Fluoride Cement K940459
Aeliteflo K955292

DEVICE DESCRIPTION: FLOWABLE COMPOSITE is a one-component, moderately filled, visible light cured dental composite restorative material.

FLOWABLE COMPOSITE 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 FLOWABLE COMPOSITE meet ISO Standard 4049.

INTENDED USE: FLOWABLE COMPOSITE is used for: Filling of defects and undercuts in crowns, inlays and onlays; As a 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 and V restorations; Conservative Class 1 restorations; and Margin correction/adjustment of composite crowns for indirect laboratory use.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in FLOWABLE COMPOSITE 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 FLOWABLE COMPOSITE in legally marketed predicate devices and the performance data provided support the safety and effectiveness of FLOWABLE COMPOSITE for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 1998

Mr. P. Jeffrey Lehn
Associate Director
Corporate Compliance
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17404

Re: K981965
Trade Name: Flowable Composite
Regulatory Class: II
Product Code: EMA
Dated: June 3, 1997
Received: June 4, 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 (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.

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: K981965

Device Name: FLOWABLE COMPOSITE

- 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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ___

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981965