SEP 21 1998

DENTSPLY

510(k) SUMMARY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
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(717) 845-7511
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K982394

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

CONTACT: P. Jeffery Lehn

DATE PREPARED: JUL 08 1998

TRADE OR PROPRIETARY NAME: PRIME & BOND® NT™ DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM

CLASSIFICATION NAME: Resin tooth bonding agent 872.3200

PREDICATE DEVICES:
Prime & Bond® 2.1 Dual Cure Universal Dental Adhesive System K962348, K964525

DEVICE DESCRIPTION: PRIME & BOND® NT™ BONDING AGENT is a one-component, no-mix visible light-curable dental bonding agent that contains fluoride. When used with the activator provided (K964525), the bonding agent may be self-cured or dual-cured.

The physical properties of PRIME & BOND® NT™ DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM are comparable to Prime & Bond® 2.1 Bonding Agent (K962348).

INTENDED USE: PRIME & BOND® NT™ DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM is used for Direct composite and compomer restorations; Composite, ceramic and amalgam repairs; Cavity varnish for use with fresh amalgam; Indirect restorations-dual cure, inlays, onlays, veneers, crowns and bridges; Endodontic post cementation; and Adhesive bonding of direct amalgam restorations.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in PRIME & BOND® NT™ DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM have either been used in predicate dental devices or have been found safe for dental use.

PRIME & BOND® NT™ BONDING AGENT (cured material) was tested for cytotoxicity (growth inhibition test) and found to be acceptable.

We believe that the prior use of the components of PRIME & BOND® NT™ DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM in legally marketed predicate devices, the performance data, and the results of biocompatibility testing support the safety and effectiveness of PRIME & BOND® NT™ DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 1998

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: K982394
Trade Name: Prime & Bond® NT™ Dual Cure Universal Dental Adhesive System
Regulatory Class: II
Product Code: KLE
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 (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,

Susan Runner

for 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: K982394

Device Name: PRIME & BOND® NT™ DUAL CURE UNIVERSAL DENTAL ADHESIVE SYSTEM

- Direct composite and compomer restorations
- Composite, ceramic and amalgam repairs
- Cavity varnish for use with fresh amalgam
- Indirect restorations: Dual Cure, inlays, onlays, veneers, crowns and bridges
- Endodontic post cementation
- Adhesive bonding of direct amalgam restorations

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 K982394