SEP 22 1999

DENTSPLY

510(k) SUMMARY

NAME & ADDRESS:

K992518

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: JUL 27 1999

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

CLASSIFICATION NAME: Resin tooth bonding agent 872.3200

PREDICATE DEVICE: Prime & Bond® NT™ Universal Dental Adhesive System K982394

DEVICE DESCRIPTION: PRIME & BOND® NT™ DENTAL ADHESIVE SYSTEM is a one-component, no-mix visible light-curable dental bonding agent that contains fluoride.

INTENDED USE: The **new** Indication for Use for PRIME & BOND® NT™ DENTAL ADHESIVE SYSTEM is for use in conjunction with pit and fissure sealant.

TECHNOLOGICAL CHARACTERISTICS: PRIME & BOND® NT™ Dental Adhesive System is unchanged from the initial submission, K982394. This premarket submission is for a new intended use only.

We believe the fact that the device is unchanged from the predicate device (K982394) and that the performance data provided support the safety and effectiveness of PRIME & BOND® NT™ DENTAL ADHESIVE SYSTEM for the new indication for use.

Substantial Equivalence Comparison:

Prime & Bond® NT™ Dental Adhesive System is unchanged from the initial submission, K982394. This premarket submission is for a new intended use only.

Performance Data:

Dyract® Seal Compomer Pit & Fissure Sealant with NRC™ Non-Rinse Conditioner pretreatment, combined with PRIME & BOND® NT™ DENTAL ADHESIVE, develops an adhesive strength to enamel that is comparable to Dyract® Seal Compomer Pit & Fissure Sealant with an acid etchant pretreatment.

PRETREATMENT USED	ADHESION (24h) MPa
Nupro® Prophylaxis Paste, Medium Grit; rinse; dry; NRC™ Conditioner; 20"; dry; DyractSeal™ Pit and Fissure Sealant	8.79 ± 1.56
Nupro® Prophylaxis Paste, Medium Grit; rinse; dry; Etchgel Conditioner; 20"; rinse; dry; DyractSeal™ Pit and Fissure Sealant	12.93 ± 1.41
Nupro® Prophylaxis Paste, Medium Grit; rinse; dry; NRC™ Conditioner; 20"; dry; Prime & Bond® NT™ Adhesive; 20"; DyractSeal™ Pit and Fissure Sealant	11.09 ± 2.38
Nupro® Prophylaxis Paste, Medium Grit; rinse; dry; Etchgel Conditioner; 20"; rinse; dry; Prime & Bond® NT™ Adhesive; 20"; DyractSeal™ Pit and Fissure Sealant	13.01 ± 3.21

It is essential for the clinical success of a pit and fissure sealant, that the sealant develops a durable adhesion resulting in long-term protection , e.g., against microleakage. Therefore the long-term adhesion of DyractSeal was tested under various pretreatments.

Time (months)	Adhesion (MPa) of Dyract® Seal Pit & Fissure Sealant to enamel using:	
	DeTrey® Conditioner 36*	NRC™ Non-Rinse Conditioner and Prime & Bond® NT™ Dental Adhesive
0	14.1 ± 1.8	12.5 ± 2.1
2	12.0 ± 0.64	9.4 ± 2.0
4	11.7 ± 1.0	11.7 ± 0.6
6	11.1 ± 1.8	11.2 ± 2.6
8	12.5 ± 1.8	10.5 ± 1.7
12	10.5 ± 2.2	9.4 ± 2.2

*36% phosphoric acid gel

In addition to the above data, a micromorphology study was also conducted; the results showed good bonding properties. The study report can be found in Exhibit A.

Safety Data:

Prime & Bond® NT™ Dental Adhesive System is unchanged from the initial submission, K982394. This premarket submission is for a new intended use only.

The safety of the device has not been affected.

We believe the fact that the device is unchanged from the predicate device (K982394) and that the performance data provided, support the safety and effectiveness of PRIME & BOND® NT™ DENTAL ADHESIVE SYSTEM for the new indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 1999

Mr. P. Jeffery Lehn
Director, Corporate Compliance and Regulatory Affairs
Dentsply International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K992518
Trade Name: Prime & Bond® NT™ Universal Dental Adhesive System
Regulatory Class: II
Product Code: EBC
Dated: July 27, 1999
Received: July 28, 1999

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

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) 594-4690. 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 Co
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ENCLOSURE A

K992518

Revised 9/14/99

510(k) NUMBER (IF KNOWN): K992518

DEVICE NAME: PRIME & BOND® NT™ DENTAL ADHESIVE SYSTEM

INDICATIONS FOR USE:

Addition of New Indication: To be used in conjunction with pit and fissure sealant

Current Indications, K982394:

- 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

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K992518

Prescription Use ✓
(Per 21 CFR 801.109)