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Page 1 of 2

DENTSPLY

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: November 11, 1996

TRADE NAME: PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT WITH ACTIVATOR

COMMON OR USUAL NAME: Bonding agent

CLASSIFICATION NAME: Resin tooth bonding agent 21 CFR, 872.3200

PREDICATE DEVICES: Scotchbond M.P. Plus Dental Adhesive System K942493
Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent K962348

DESCRIPTION AND INTENDED USE: Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent is a one-component, no-mix visible light curable dental bonding agent that contains fluoride. No changes have been made to Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent in design, material, chemical composition or manufacturing process.

A new accessory, Prime & Bond™ Self-Curing Activator, can be used with Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent, enabling the practitioner to use self-cure bonding techniques for the current Indications for Use of the Bonding Agent where a dual-cured adhesive may be desired.

Also because of the self-cure capability, use of the Bonding Agent and Activator together allows adhesion of amalgam restorations to tooth structures, which is a NEW INDICATION FOR USE.

Prime & Bond™ Self-Curing Activator is an acetone/ethanol solution of an aromatic sulfinic acid salt. When applied in combination with Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent, the Activator initiates a self-cure, free radical polymerization of the monomers and oligomers present in the Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent.

TRADE NAME: PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT
WITH ACTIVATOR

TECHNOLOGICAL CHARACTERISTICS: No changes have been made to Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent in design, material, chemical composition or manufacturing process.

All of the components of the Prime & Bond™ Self-Curing Activator have been used in legally marketed devices or have been proven to be safe for dental use.

We believe the fact that Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent has not been changed, the prior use of the Prime & Bond™ Self-Curing Activator components in predicate devices, the performance data presented for the use of Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent with the Prime & Bond™ Self-Curing Activator, and the cytotoxicity test results of the Activator active ingredient support the safety and effectiveness of Prime & Bond™ 2.1 Multipurpose Dentin/Enamel Bonding Agent when used with Prime & Bond™ Self-Curing Activator for the new indications for use.