

K960348

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DENTSPLY

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DATE PREPARED: June 17, 1996

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

COMMON OR USUAL NAME: Bonding agent

CLASSIFICATION NAME: Resin tooth bonding agent 21 CFR, 872.3200

PREDICATE DEVICES:

Prime & Bond™ 2.0 Multipurpose Dentin/Enamel Bonding Agent K960823

Fluoride-PSA Prime/Adhesive K941572

Prime & Bond Direct Composite Bonding Agent K931812

DEVICE DESCRIPTION: PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT is a one-component, no-mix, visible light curing dental bonding agent that releases fluoride.

The new bonding agent consists of a mixture of monomers, fluoride, and an adhesion promoter in an acetone solution. Additionally, the mixture contains photo-initiators, accelerators and polymerization inhibitors which allow for a shelf stable material that can be polymerized using visible light energy.

Once the tooth to be restored has been prepared, PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT is applied, left on the surface for 20 seconds, air dried, and then light cured for 10 seconds. A second application may be applied for direct restorative procedures, but this is not required for indirect procedures.

PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT and Prime & Bond™ 2.0 Multipurpose Dentin/Enamel Bonding Agent (K960823) are comparable in direct composite bond strength (dentin, enamel, adhesive repair), indirect composite bond strength (metal appliances, inlays, onlays, veneers), and microleakage values. PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT has a high degree of marginal integrity and a reduced incidence of post operative hypersensitivity.

INTENDED USE: PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT is a self-priming bonding agent for use in direct and indirect restorative procedures, for adhesive repairs of amalgams, porcelain/metal and composite, and for an adhesive cavity varnish. The intended uses of PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT are identical to the intended uses of Prime & Bond™ 2.0 Multipurpose Dentin/Enamel Bonding Agent (K960823).

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

TECHNOLOGICAL CHARACTERISTICS: All of the components of PRIME & BOND™ 2.1 SELF-PRIMING DENTIN/ENAMEL BONDING AGENT have been used in the DENTSPLY predicate devices, Prime & Bond™ 2.0 Multipurpose Dentin/Enamel Bonding Agent (K960823) and Fluoride-PSA Prime/Adhesive (K941572). These devices were evaluated for cytotoxicity and for irritation and found to be non-cytotoxic and a non-irritant. Due to the similarity of the new formulation to the primary predicate device (K960823), we believe that additional toxicity testing for PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT is unnecessary.

We believe that the prior use of the PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT components in predicate devices, the near identical formulation to the predicate device, the performance data and fluoride release data presented, and the results of toxicity testing on predicate devices, support the safety and effectiveness of PRIME & BOND™ 2.1 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT for the intended uses.