

510(k) SUMMARY

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TRADE OR PROPRIETARY NAME:
PRIME & BOND™ 2.0 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT

COMMON OR USUAL NAME: Bonding agent

CLASSIFICATION NAME: Resin tooth bonding agent 21 CFR, 872.3200

LEGALLY MARKETED DEVICE:
Prime & Bond™ Direct Composite Bonding Agent K931812
Prime & Bond - New Uses K951864

DEVICE DESCRIPTION: PRIME & BOND™ 2.0 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT is a one-component, no-mix visible light curable dental bonding agent.

The new bonding agent consists of a mixture of monomers 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™ 2.0 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT is applied, left on the surface for 20-30 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.

INTENDED USE: PRIME & BOND™ 2.0 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.

TECHNOLOGICAL CHARACTERISTICS: All of the components of PRIME & BOND™ 2.0 SELF-PRIMING DENTIN/ENAMEL BONDING AGENT have been used in Dentsply legally marketed predicate devices.

In K931812, Prime & Bond™ Direct Composite Bonding Agent was 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 this predicate device, we believe that additional toxicity testing for PRIME & BOND™ 2.0 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT is unnecessary.

We believe that the prior use of the PRIME & BOND™ 2.0 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT components in predicate devices, the performance data presented, and the results of toxicity testing on predicate devices, support the safety and effectiveness of PRIME & BOND™ 2.0 MULTIPURPOSE DENTIN/ENAMEL BONDING AGENT for the intended uses.

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