

K962065

**510(K) SUMMARY**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

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Trade Name: 3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base  
Common Names: cavity liner, lining cement, bonded base  
Classification Name: dental cement other than zinc oxide-eugenol  
(21 CFR 872.3275(b))

Predicate devices: Vitrabond Light Cure Glass Ionomer Liner (K882821)  
Bisco Cavity Cleanser (K915668)  
Uni-Etch™ (part of One-Step Universal Dentin Adhesive)

3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base is comprised of a powder and a liquid component. The powder component is a light sensitive fluoro-aluminosilicate glass. The liquid component is a light sensitive polyalkenoic acid. The composition is a true glass ionomer exhibiting the major characteristics of glass ionomer products - it bonds to tooth structure, releases fluoride, and is a biocompatible material. Additionally, Vitrebond liner/base offers the unique combination of a prolonged working time with a very short set time achieved by exposure to light from a dental visible light curing unit. Polymerization by light exposure not only eliminates the set time waiting period common to auto set liners, it also provides enhanced mechanical and physical properties. 3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base is indicated for lining and basing applications under composite, amalgam, ceramic, and metal restorations.

3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base has been changed very little since it was introduced globally over seven years ago. It is going through the 510(k) process now to add some labeling claims. In all other respects it is substantially equivalent to Vitrabond (K882821).

The toxicology and histology data discussed in K882821 still applies, since the chemical composition is virtually unchanged. The fact that this material has been used globally for years with excellent results confirms the fact that this material is safe and effective for its intended uses.

3M™ Vitrebond™ Light Cure Glass Ionomer Liner/Base is substantially equivalent to the Bisco Cavity Cleanser (K915668) and Uni-Etch™ on the basis that they contact dentin and make a similar claim.