K960954

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for modifications to its 510(k) submissions for dental cement material, tradenamed Ketac-Bond® Aplicap® (K874788) and Ketac-Silver® Aplicap (K843566), to create slightly modified glass ionomer cement material, referred to by the tradename Ketac-Molar® Aplicap®. The reason for this modification is to provide for an improved compressive strength. Ketac-Molar® Aplicap® is a glass ionomer cement material indicated for the following uses: (1) linings for Class I and II cavities filled with composite; (2) core build-ups; (3) fillings in deciduous teeth; (4) fillings in Class I cavities located in non-occlusal load bearing areas; (5) fillings in Class V cavities if the aesthetics are not of primary importance; and (6) temporary fillings in Class I and II cavities.

ESPE is claiming substantial equivalence to its previously cleared Ketac-Bond® Aplicap® and Ketac-Silver® Aplicap® products. These products have similar intended uses and, in the case of Ketac-Bond® Aplicap®, the same principal ingredient composition.

To support substantial equivalence to predicate products, the physical and technical characteristics, as well as the water soluble fluoride content, of Ketac-Molar® Aplicap® have been compared to those of Ketac-Bond® Aplicap® and Ketac-Silver®

Aplicap®. Ketac-Molar® Aplicap® meets the requirements of relevant DIN and ISO standards for dental cement.

ESPE's 510(k) has been submitted on March 6, 1996, by Dr. Barbara Wagner at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).