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II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

K963737

ESPE is submitting a 510(k) premarket notification for its compomer luting cement, tradenamed Hycem® Aplicap®. Hycem® Aplicap® is intended for final cementation of restorations composed of all classes of materials, including for cementation of crowns, bridges, inlays/onlays, pins and screws, and brackets and bands.

ESPE is claiming substantial equivalence to Dentsply Caulk's Advance™ Hybrid Ionomer Cement. These products have the same intended use and similar composition.

To support the substantial equivalence to predicate products, the composition and the physical and technical characteristics of Hycem® Aplicap® have been compared to those of Advance™ Hybrid Ionomer Cement. Hycem® Aplicap® meets the requirements of relevant DIN and ISO standards for dental cement.

ESPE's 510(k) has been submitted on September 17, 1996 by Dr. Barbara Wagner at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).