

K962440

SEP 11 1986

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for modifications to its 510(k) submission for tooth shade resin material, tradenamed Pertac®-Hybrid® (K900510). The modified materials, referred to by the tradenames Pertac® II and Pertac® II Aplitip®, are intended as composite filling materials, and are indicated for the following uses: (1) fillings in Class I, III, IV, V and small Class II cavities; (2) fillings in deciduous teeth; (3) eroded and abraded cervical areas (wedge-shaped defects); (4) fabricating indirect anterior laminate veneers and tooth colored inlays; and (5) repairing facings on crowns and bridges.

ESPE is claiming substantial equivalence to its previously cleared Pertac®-Hybrid® product. These products have almost identical intended uses and similar ingredient compositions. To support substantial equivalence to predicate products, the physical and technical characteristics of Pertac® II/Pertac® II Aplitip® have been compared to those of Pertac®-Hybrid®. In addition, certain tests have been performed by the manufacturer, Peroxid-Chemie, on the peroxide component added to Pertac®

II/Pertac® II Aplitip® to confirm safe use of the product, including skin irritation, eye irritation, Ames and acute toxicity.

Pertac® II and Pertac® II Aplitip® meet the requirements of relevant DIN and ISO standards for dental composite material.

ESPE's 510(k) has been submitted on June 19, 1996, by Dr. Barbara Wagner at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).