K963735

II. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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ESPE is submitting a 510(k) premarket notification for its 4-component system for intraoral adhesive repair of porcelain and composite restorations and pretreatment for adhesive cementation, trade named CoJet™-System. The CoJet™-System's intraoral adhesive restoration repair and adhesive cementation uses include:

- adhesive repair of defects in porcelain
- adhesive repair of defects in porcelain with exposed metal
- adhesive repair of defects in composite
- adhesive repair of defects in composite with exposed metal
- conditioning of metal restorations prior to cementation, e.g., crowns, bridges, inlays, onlays, root posts, core posts, etc.
- conditioning of porcelain or composite restorations prior to adhesive cementation, e.g., inlays, onlays, laminate veneers, etc.

The CoJet™-Sand used in the CoJet™-System is ESPE's 510(k)-cleared Rocatec®-Plus (K913857), except for the addition of a pigment, iron oxide (C.I. 77491), and the use of more finely grained sand (30 μm versus 110 μm). The iron oxide pigment is a medical device-listed color additive at 21 C.F.R. § 73.3125, and has been used in the following ESPE 510(k)-cleared products: Photac®-Fil Aplicap® (K925027), Dimension materials (K960547), Pertac®-Hybrid (K900510), Sono-Cem (K913966), and Ketac-Endo Aplicap® (K911061). CoJet™-Sand also is

substantially equivalent to the aluminum oxide material used in the Microetcher™ Dental Bonding System (K902836/A). The silane coupling agent in the System is ESPE's 510(k)-cleared ESPE®-SIL (K913965), and the bonding material is ESPE's 510(k)-cleared Visio®-Bond (K790833/B). Finally, the Opaquer is a component of Visio®-Gem, ESPE's 510(k)-cleared crown and bridge veneer material for light polymerization (K833757). The only modification to these previously cleared ESPE components is that they will be prepared and used intraorally, rather than prepared extraorally, for subsequent intraoral use. One of the predicates for CoJet™-Sand, Microetcher™, however, has been cleared for intraoral preparation and use. Performance data demonstrate that the products' performance is not affected by intraoral preparation and use.

ESPE's 510(k) has been submitted on September 17, 1995 by Dr. Barbara Wagner at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).