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II. 510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

ESPE is submitting a 510(k) premarket notification for modifications to its 510(k) submissions for silicone impression material, tradenamed Permagum® (K812116) and Permagum® Garant Light (K890720), to create slightly modified impression material, referred to by the tradenames Dimension® Penta and Dimension® Garant L. For Dimension® Penta, the reason for this modification is solely to improve user convenience by allowing mixing of the impression material through use of a free-standing electronic mixing apparatus (Pentamix) and to enhance the stability of the impression material. For Dimension® Garant L, the reason for this modification is also to enhance user convenience by allowing mixing and dispensing of the impression material through use of a hand-held automatic mixing and dispensing apparatus (Garant Dispenser). Dimension® Penta and Dimension® Garant L are both polyvinyl siloxane impression material, composed of a base paste and catalyst, <sup>\*</sup> used to make impressions of inlay, onlay, crown and bridge preparations, and edentulous jaws.

ESPE's 510(k) submission also includes adhesive material, tradenamed Polyvinyl Siloxane Adhesive, which is a modification of ESPE's previously cleared Permagum® Adhesive (K881838). The reason for the modification in adhesive material is to enhance the user's ability to create a uniform layer of the adhesive on the tray, to enhance the product's adhesion power and to

accommodate workplace preferences. Polyvinyl Siloxane Adhesive is intended to assure adhesion of impression material to the impression tray and to avoid deformation during impression taking.

For Dimension® Penta and Dimension® Garant L, ESPE is claiming substantial equivalence to its previously cleared Permagem® and Permagem® Garant Light products, respectively. Both sets of products have the same intended use and the same principal ingredient composition. The percentage at which certain components are present in the impression material, however, has been changed in order to improve product viscosity and mixability of the impression material to enable use of the products in conjunction with an automatic mixing apparatus. In addition, several new pigments have been added to the base paste and catalyst to allow for varying impression colors. Finally, several ingredients at relatively insignificant amounts have been added to the new material in order to enhance product stability and mixability.

For Polyvinyl Siloxane Adhesive, ESPE is claiming substantial equivalence to its previously cleared Permagem® Adhesive. Both products have the same intended use, and two of the three product ingredients remain the same. The percentage at which two of the three product components are present in the adhesive material, however, has been slightly changed in order to

enhance the user's ability to create a uniform layer of the adhesive on the tray, and also to enhance the product's overall adhesion power. In addition, one ingredient has been substituted for another in order to accommodate workplace preferences.

To support substantial equivalence to predicate products, the physical and performance characteristics of Dimension® Penta have been compared to those of Permagum®, and the physical and performance characteristics of Dimension® Garant L to those of Permagum® Garant Light. The relevant performance characteristic of Polyvinyl Siloxane Adhesive (adhesion power) has been compared to that of Permagum® Adhesive. Dimension® Penta and Dimension® Garant L meet the requirements of relevant DIN, ISO and ADA standards for impression material.

ESPE's 510(k) has been submitted on February 5, 1996, by Dr. Barbara Wagner at Am Griesberg 2, D-82229 Seefeld, Germany (011-49-8152-700395).