

Summary of Safety and Effectiveness

K961284

Kolor + is a filled paste containing the same components as Herculite XRV (Herculite XRV received market clearance under 510(k) K943642). The material is highly pigmented in eleven distinct shades by incorporation of the same pigments employed in XRV. The dentist will utilize this material by adding a small portion (1 - 2 drops) to a composite filling material. This effects the material only in coloration. Since the components of Kolor + are identical to XRV and the ratio of components are similar, the addition of this colorant has no discernible affect upon the performance of the composite material.

There are several products currently on the market for the same intended purpose. Many of them are referred to under different names such as colorants, shade modifiers, and stains. However, all of these products have the same intended use (i.e. modifying the shade of the composite). The physical properties of Kolor + have been evaluated and compared to three predicate devices. A comparison chart of the test results has been included in exhibit E.

Kolor + has under gone biocompatibility testing at the NAmSA Laboratories testing facility. The final composition of Kolor + was evaluated for cytotoxicity. In this test it was determined that Kolor + was non-toxic. Since the components of Kolor + are the same as those used in Herculite XRV further biocompatibility testing was not necessary. All biocompatibility testing conducted to support the safety of Herculite XRV indicated that it was both non-toxic and a non-irritant. The results of the cytotoxicity test for Kolor +, the formulation for Herculite XRV and the biocompatibility testing results for Herculite XRV have been included in exhibit F.

Product literature from several equivalent products has been provided in exhibit G. Also included is a copy of the FDA 510(k) market release letter for Herculite XRV.