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K963805

510 (k) Notification for Prodigy Autocure Restorative and Core Buildup Material

510 (k) Summary

Statement of Safety an Effectiveness

BACKGROUND

In the spring of 1995, Kerr began distribution of a new visible light cured composite restorative material under the tradename, **Prodigy** (Reference: **K944659**). The product gained rapid acceptance and is now one of the market leaders among light cure composite restoratives. The reason for this success, is that Prodigy is the current embodiment of a fourth generation of continuously improving anterior/posterior restorative technology. The ancestors include **Herculite Condensable Posterior Composite** (1984), **Herculite XR** anterior/posterior composite (1986), **Herculite XRV** universal composite in vita shades (1992). Prodigy's unique resin chemistry results in an ideal working viscosity, while the small particle hybrid filler provides superior durability and polishability. All of this with the life-like aesthetics of Vita shading has made Prodigy the restorative material of choice of thousands of clinicians.

PRODIGY AC

In response to customer feedback and many requests from the field, Kerr has developed **Prodigy Autocure Restorative and Core Buildup Material**. This material is identical to light cure Prodigy except for minor modifications in the polymerization chemistry and the addition of a small amount of a Fluoride release agent. Specifically, the camphorquinone / amine visible light initiation components were replaced with the traditional chemical cure additives, Benzoyl Peroxide in the catalyst paste and DHEPT [N,N-Di-(2-hydroxyethyl)-4-toluidine] in the base paste. To provide the benefits associated with a Fluoride releasing material, 2 % by weight Sodium Hexafluorosilicate (Na_2SiF_6) was added to all paste formulations. Kerr intends to market this device in two distinct package configurations. The first, the Prodigy AC autocure composite restorative material, will be offered in a kit containing one 5 gram jar of catalyst paste along with one 5 gram jar of each of three base paste shades (Light, Universal, and Dark). The second, Prodigy AC Core Buildup Material, tentatively being referred to as ProCore, will be supplied in a kit containing one 5 gram syringes each of the catalysts (High and Low Viscosity), and one 5 gram syringe of a dual cure White base paste (This paste formula will be light and chemically activated.). A detailed description of both of these kit contents is provided later in this submission.

SAFETY

The safety and biocompatibility of the cured state methacrylate monomer based, glass filled composite restorative materials is well established in the dental community. Since the formulation of this product is so similar to the original Prodigy material (Ref: K944659) there is no reason to suspect that the slight modifications made to additive components would adversely effect the safety and biocompatibility of this device. Copies of the original Prodigy test results are being included elsewhere in this submission for your review.

EFFECTIVENESS

The efficacy of this product, with respect to it's suitability to it's intended purpose, is demonstrated by the fact that when tested in side by side comparison with several predicate devices currently on the market, it performed as well or better than the predicate devices. Results of this comparison testing is provided elsewhere in this submission.