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510 (k) Summary

Statement of Safety an Effectiveness

Kerr Foundation Indirect Composite Resin

Submitter

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Device Name

Trade Name: Foundation Indirect Composite Resin
Common Name: Dual cured indirect composite restorative material
Classification Name: Tooth Shade Resin Material, Class II, per 21 CFR 872.3690

Devices for which Substantial Equivalence is Claimed

belleGlass HP (Kerr Corp.), Concept (Williams Dental), Art Glass (Hereas Kulzer GmbH)

BACKGROUND

Kerr introduced a new composite resin based Crown and Bridge fabrication system called **belleGlass HP** in May, 1996 (Reference K955331). This system is comprised of all of the components necessary for a dental laboratory to fabricate composite resin-based Crowns and Bridges and cure them using both light activation combined with a final heat and pressure curing cycle in the belleGlass HP automatic curing device. (Complete existing Instructions for Use of this product is supplied elsewhere in this submission.)

One of the sets of composite materials used in this process is referred to as Opaque Dentin Pastes. These consist of 16 light cured only pastes which match the Vita Shade Guide used with Vita Porcelain powders. These materials proved adequate, but because of their single cure mode (visible light activation) they may not be durable enough to withstand the constant abuse associated with long term residence in the oral environment. Therefore, a more durable, yet esthetically acceptable material was sought.

FOUNDATION INDIRECT COMPOSITE

Kerr's Foundation consists of a reformulation of the existing Opaque Dentin Pastes in order to increase durability and material stability in the mouth. This reformulation consists essentially of two significant modifications:

1. The addition of 0.15 weight percent of VAZO 88 (Azobiscyclohexane Carbonitrile), a heat activated polymerization initiator.

2. The replacement by 56 weight percent of the Barium Alumoborosilicate glass filler with a corresponding amount of Magnesium Aluminosilicate, a low coefficient of thermal expansion glass filler.

This combination of initiator and glass filler modifications results in a composite resin-based restorative material that exhibits half the thermal expansion characteristics of existing products and produces reductions in Volume % Polymerization Shrinkage in a range of 33 to 70 %.

SAFETY

The safety of Kerr Foundation Indirect Restorative has been demonstrated by subjecting cured samples of the material to various types of biocompatibility tests as recommended in the ISO 10993 biocompatibility guidance standard. These tests were conducted by an independent laboratory which specializes in safety and toxicity evaluation. The tests include:

1. Ames Mutagenicity Assay
2. Cytotoxicity Study (Elution Test, USP 23)
3. Kligman Maximization Study (Tissue Sensitization)
4. Intramuscular Implantation Test (Tissue Irritation)

EFFICACY

Effectiveness or suitability to the intended purpose of Kerr Foundation has been demonstrated by a combination of in-house testing and side by side test comparisons to predicate devices currently on the market. Results of this bench testing indicates that Kerr Foundation Indirect Composite performs as well or better than three predicate devices currently on the market

Results of this testing is included elsewhere in this submission.