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510 (k) Summary

Statement of Safety an Effectiveness

Kerr TempFil C&B Temporary Restorative Material

Submitter

Sybron Dental Specialties Inc.
1717 West Collins Avenue
Orange, CA 92867
(714) 516-7486 - Phone
(714) 516-7488 - FAX
William R. Pike - Contact Person

Device Name

Trade Name: TempFil C&B
Common Name: Temporary Crown and Bridge Material
Classification Name: Crown and Bridge Temporary, resin, per 21 CFR 872.3770

Devices for which Substantial Equivalence is Claimed

Luxatemp (DMG), Protemp Garant (ESPE), and Integrity (L. D. Caulk)

BACKGROUND

Provisional or temporary restorative materials are used in dentistry for treatment procedures not intended to be permanent or final. The purpose of the temporary material is to protect a prepared tooth surface during the interim period until the permanent restoration is available. An example of this interim period is the time that passes while porcelain or metal prosthetic devices are being fabricated in a dental laboratory. Another purpose of a temporary restoration is to provide an esthetically pleasing appearance for the patient during this interim period.

TEMPFIL C&B

Kerr's TempFil F is designed to fulfill all of the requirements of a successful temporary restorative material. These requirements are itemized below:

1. Ease of placement. TempFil C&B is supplied in a double barreled cartridge container which can be used with any of the currently available cartridge dispensers (i.e. Kerr's Extrude mixer/extruder dispenser) that will accept 1:1 mix ratio plungers. This allows the dentist to simultaneously mix and dispense the material directly into the impression or crown form.

2. Convenience. The automatic mixing tips eliminate the need for spatulae, mixing pads and placement instruments.

SAFETY

The safety of Kerr TempFil F 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 (Agarose Overlay)
3. Kligman Maximization Study (Tissue Sensitization)

EFFICACY

Effectiveness or suitability to the intended purpose of **Kerr TempFil F** 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 TempFil C&B Temporary Restorative Material** performs as well or better than three predicate devices currently on the market