

K963786

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## **510 ( k ) Summary**

### **Statement of Safety and Effectiveness**

#### **Kerr TempFil F Temporary Restorative Material**

##### **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 F**

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 F is supplied in two formulations identified as Inlay and Onlay. The Inlay formula is slightly less filled and this lower viscosity paste will flow easily into the complex preparation configurations of the typical inlay type restoration. Conversely, the onlay formula, with its' higher filler loading, results in a stiffer paste more suited to the sculpting and packing associated with a typical onlay type restoration.
2. These two formulations have also been adjusted to accommodate the different service conditions experienced by the two distinct types of restoration in the oral environment. The onlay paste contains an additional crosslinking monomer not found in the inlay material. This additional crosslinking results in a harder surfaced restoration which is better able to withstand forces exerted by opposing dentition. These forces are more prevalent in an onlay type restoration.
3. Convenience. The visible light activated curing characteristic of this no mix system is quicker and easier for the dentist to accomplish than the traditional chemically cured mixed catalyst and base systems.
4. Ease of removal. Both formulations contain a monomeric component that allows the cured material to maintain the degree of elasticity required for easy removal when the final restoration is available. This elasticity helps to prevent damage to prepared margins during removal.
5. Both formulations contain a fluoride release agent to impart the benefits of fluoride even during temporary use.
6. The kit contains a syringe of Relief, a water soluble gel that is designed to prevent adhesion to glass ionomer and composite resin based liners placed under the TempFil F restorative.

**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 F Temporary Restorative Material** performs as well or better than **Fermit** (Mfg. by Vivadent), **E-Z Temp** (Mfg. by Cosmedent), **Clip** ( Mfg. by Voco), three predicate devices currently on the market