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# 510 ( k ) Summary

## Statement of Safety an Effectiveness

## Kerr Resilient Denture Liner

**BACKGROUND**

The success of complete or partial dentures depends upon esthetics, comfort and function. Unfortunately, the high stress concentrations encountered during function can adversely affect the health of supporting tissues. Chronic soreness can be a significant problem for many denture patients. The problem results from the soft, denture bearing tissues being confined between the hard denture base and the hard bones of maxilla and mandible.

The use of Resilient Liners is an attempt to distribute the functional and non-functional stress more evenly with the Resilient Liner acting as a shock absorbing appliance due to their elastic nature.

Dentistry traditionally uses Resilient Liners to treat denture wearing patients with:

Ridge atrophy
Ridge resorption
Bony undercuts
Bruxing tendancies
Congenital or acquired defects
Xerstomia
Dentures opposing natural dentition

In application, Resilient Liners fall into three chemical categories; plasticized polymers or copolymers, silicone rubbers and fluoroelastomers. All three classes were chosen due to their relative ease of manipulation and their ability to maintain resiliency over an extended time in the oral cavity. None of these classes can be considered permanent as they lose their resilience with time, become fouled by the oral envirinment or suffer bond failure from the hard denture base material. At this point the resilient material must be removed and replaced.

The Kerr Resilient Liner fits into the silicone category of products such as Prolastic ( Young Dental ) and Molloplast-B ( Buffalo Dental Mfg. Co. ) and is substantially equivalent to them with respect to safety and efficacy.

**Kerr Resilient Denture Liner** consists of two Polvinylsiloxane resin based paste components which interact and polymerize to produce a gingivally characterized elastomer. It is supplied in two 50 ml double barrel cartridges containing 25 ml. each of both the catalyst and base pastes. These cartridges are designed to be used with the Kerr Extruder Mixing Gun ( Sold seperately - Covered in 510 ( k ) No. K940379 ). The cartridges attach to disposable static mixing tips which mix the catalyst and base pastes by forces exerted by the Kerr Extruder prior to application of the soft liner material.

The safety of Kerr Resilient Denture Liner 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. Implantation Test ( Tissue Sensitization )

Effectiveness or suitability to the intended purpose of **Kerr Resilient Denture Liner** 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 Resilient Denture Liner** performs as well or better than **Molloplast-B** and **Coe Supersoft,** two predicate devices currently on the market