

K96469Z

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### 510(k) Summary

The following summary regarding 510(k) safety and effectiveness information for the Perfectim dental impression materials device, regulated under 21 C.F.R. Section 872.3660, was prepared November 4, 1996 and is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 and 21 C.F.R. Section 807.92.

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#### Classification Name:

Impression material

#### Usual Name:

Dental impression material

#### Proprietary Name:

Perfectim



## Predicate Devices

The Perfectim line of dental impression materials have the same technological, safety, and effectiveness characteristics, and are substantially equivalent to, the following predicate devices:

<u>PERFECTIM PRODUCT</u>	<u>PREDICATE DEVICE</u>
Blue Velvet	K930248; K871409; K781083
30 Second Blue Velvet	K930248; K871409; K781083
Flexi-Velvet	K930248; K871409; K781083
Single Phase Body	K872745; K871409; K781083
Final Wash	K801380; K871409; K781083
Preliminary Phase	K930248; K871409; K781083
Secondary Wash	K801380; K871409; K781083
Putty	K801380; K781083

## Intended Use

To take dental impressions.

## Description of Device

This 510(k) application is for a line of dental impression materials. Vinyl polysiloxane impression materials have been used in the dental field since 1973. There are presently at least twelve manufacturers worldwide of this type impression material and more than 30 companies selling impression products under private label. Based upon the total impression market, which would include all types of impression materials used, the vinyl addition products have gained the majority share according to current trade reports.

Clinical studies as well as scientific evaluations have shown that the handling characteristics and the physical properties of the vinyl polysiloxane impression materials are superior to all previous impression materials. With the many impression techniques that are used in dentistry today, the vinyl addition system manufacturers have developed a great variety of different materials to satisfy these diverse requirements.

To create these various viscosities and rheological changes in the vinyl system, the type of filler used is changed. Radiopacity can be added by using a small percentage of barium sulfate in the filler addition (K872745, July 1987). Thixotropy to overcome the uncontrolled flow of impression materials which can cause gagging can be accomplished by altering the filler system. Instead of using extending fillers, bulking fillers are used. Aeorsil is an example of such a filler.

Fillers generally are not involved in the chemical reaction between the polymer, crosslinker and platinum complex. The filler particles interspersed between the silicone rubber matrix can alter the viscosity and durometer as well as the elasticity and tear strength of the set material. The efficacy and safety of the product is not altered since the addition silicone reaction is not dependent on the fillers used. The excellent dimensional stability of the vinyl system is also unaffected.

The available fillers that can be used in formulating vinyl polysiloxane impression systems are numerous and each one has a specific characteristic. For example, silica is available in several forms. The crystalline type, the amorphous type, the fumed type or the diatomaceous type all have different characteristics when used in system design. When more than one silica is used in a system the change in rheology can be as a result of the properties imparted by each filler.

A further filler that can be used is combining the fumed silica with magnesium silicate, creating a rheologically altered impression material that is very thixotropic, yet fluffy and non-flowing except when some external force is applied. The resultant material can be used for impressions without the inconvenience of uncontrolled flow, which in many instances cause gagging.

Vinyl addition silicone products are used in other health related fields such as rehabilitation and occupational therapy for scar control after primary wound healing and in hearing restoration with externally worn hearing aids by the use of impressions of the outer and part of the middle ear. To our knowledge no reports have been published indicating any untoward reactions when vinyl polysiloxane materials are used in any application including the high volume usage in the dental field.

When used intraorally in dentistry, the impression is contaminated with saliva and blood. Vinyl addition impressions can be disinfected with any hospital level disinfectant or aqueous sterilant to prevent the spread of pathogens from the dental office environment to the dental laboratory technician, thus eliminating possible cross contamination.