

K964040

DEC - 6 1996

510(k) SUMMARY

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NAME & ADDRESS:

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TRADE NAME: TRUBYTE® SOFT RELINE SYSTEM

CLASSIFICATION NAME: Relining, repairing or rebasing denture base resin

PREDICATE DEVICES:	New Per-Fit Improved	K901621
	Molloplast B	Unknown
	PermaSoft	K933468

DEVICE DESCRIPTION: The TRUBYTE® SOFT RELINE SYSTEM consists of three components: TRUBYTE® Soft Reline Material, TRUBYTE® Soft Reline Bonder, and TRUBYTE® Adhesive Remover.

TRUBYTE® Soft Reline Material is a silicone putty that is heat polymerizable. It is a one-component material based on an elastomer and benzoyl peroxide.

TRUBYTE® Soft Reline Bonder is a heat polymerizable methacrylate monomer and methacrylate polymer blend liquid.

TRUBYTE® Adhesive Remover is D-Limonene, a liquid food-grade solvent, intended for use in removing impression material tray adhesives.

TRUBYTE™ Soft Reline Material is bonded to the denture with the TRUBYTE® Soft Reline Bonder, packed and compressed, and then heat cured. TRUBYTE® Adhesive Remover is used to clean an existing denture prior to relining. The Adhesive is completely eliminated prior to using Soft Reline Material and Bonder.

INTENDED USE: The TRUBYTE® SOFT RELINE SYSTEM is for use as a long-term resilient lining material for removable dentures.

TECHNOLOGICAL CHARACTERISTICS: All of the components of the TRUBYTE® SOFT RELINE SYSTEM have been used in DENTSPLY predicate devices: Triad® DuaLine™ Material (K926406), Lucitone® 199 Denture Base (Pre-1976 Device), Precise™ Denture Base (K952351), and Kadon (Pre-1976 Device).

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TRADE NAME: TRUBYTE® SOFT RELINE SYSTEM

TRUBYTE® SOFT RELINE MATERIAL was evaluated and found to be non-cytotoxic, a non-irritant, non-mutagenic and a non-sensitizer. The following tests were performed on the MATERIAL: Cytotoxicity Elution Test, Primary Skin Irritation Study, Salmonella Mutagenicity Test, FHSA Regulation Acute Mucosal, and Kligman Maximization Study. The BONDER, used with the cured MATERIAL and Lucitone® 199 Denture Base, was tested by the Cytotoxicity Elution Test and found to be non-cytotoxic.

We believe that the prior use of the TRUBYTE™ SOFT RELINE SYSTEM's components in predicate devices, the performance data presented, and the results of toxicity and sensitization testing support the safety and effectiveness of TRUBYTE® SOFT RELINE SYSTEM for the intended use.

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