K962946

510(k) SUMMARY
As Required By the Safe Medical Devices Act of 1990

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE
RELY•A•BOND™

RELY•A•BOND is claimed to have solved one of the major complaints with one-step orthodontic adhesive systems, namely bond strength. It is formulated with a highly filled paste that combines with a unique primer to produce a bond strength to etched enamel that virtually eliminates bonding failures. The catalyst insures that the material reaches maximum bond strength within five minutes. The paste is comprised of a high percentage of small particles that result in a tacky consistency. Bracket flotation is said to be totally eliminated with Rely•A•BOND. The paste flows easily onto the bracket pad and spreads evenly under the pad upon placement.

DESCRIPTION OF APPLICANT PRODUCT
ORTHO-ONE™

ORTHO-ONE is identical to the Predicate Device (Rely•A•Bond). Bisco, Inc. manufacturers both products in the sam facility using the same Device Master Record. The comments noted above for the IDENTIFICATION OF THE PREDICATE DEVICE pertain to the applicant product. That is, the applicant product has solved one of the major complaints with one-step orthodontic adhesive systems, namely bond strength. It is formulated with a highly filled paste that combines with a unique primer to produce a bond strength to etched enamel that virtually eliminates bonding failures. The catalyst insures that the material reaches maximum bond strength within five minutes. The paste is comprised of a high percentage of small particles that result in a tacky consistency. Bracket flotation is said to be totally eliminated with Rely•A•BOND. The paste flows easily onto the bracket pad and spreads evenly under the pad upon placement.

INTENDED USES OF APPLICANT DEVICE

ORTHO-ONE is indicated for the adhesion of orthodontic brackets to acid etched enamel.

SCIENTIFIC CONCEPTS and SIGNIFICANT PERFORMANCE CHARACTERISTICS

ORTHO-ONE and RELY•A•BOND (K875143) are identical products manufactured in the same facility using the same Device Master Record. ORTHO-ONE is a no-mix direct bonding orthodontic adhesive. The micromechanical bond to enamel utilizes the acid etch technique and Bisco's unique composite chemistry. ORTHO-ONE will bond to metal or plastic brackets without additional conditioners.

510(k) SUMMARY (continued)
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SCIENTIFIC CONCEPTS and SIGNIFICANT PERFORMANCE CHARACTERISTICS (continued)

ORTHO-ONE, unlike conventional dental adhesives, does not require mixing in the traditional sense. That is, one is not required to mix a base and a catalyst on a mixing pad and deliver the mixed material to the mouth. The product is a two part system employing a primer and an adhesive base paste. Without mixing, the primer is applied to the tooth and the base paste is applied to the bracket. The orthodontist places the bracket against the tooth with a slight twisting motion causing the primer to activate the base paste, resulting in curing of the adhesive.

ORTHO-ONE is a traditional dental composite formulation utilizing a silica filled dimethacrylate resin base paste and an unfilled dimethacrylate primer. The adhesive cures through a conventional amine activated benzoyl peroxide initiated free radical addition polymerization.

The physical data and performance characteristics of ORTHO-ONE are statistically identical to RELY•A•BOND as would be expected. The flexural modulus (4.2 GPa), diametral tensile strength (39 MPa), and compressive strength (266 MPa) are statistically indistinguishable for the predicate and applicant product.

BIOCOMPATIBILITY of APPLICANT DEVICE

Agarose diffusion method for cytotoxicity using L-929 mouse fibroblast cells was used to assess cytotoxicity: results were negative relative to a negative and a positive control. That is, ORTHO-ONE was found to be non-toxic for L-929 mouse fibroblast cells under the described test parameters.

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380