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BISCO, INC., 1500 W. Thorndale Ave., Itasca, IL 60143
510(k) submission for **BISFIL™ 2B**

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510(k) SUMMARY

As Required by the Safe Medical Devices Act of 1990

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICE

PREDICATE DEVICE

BISFIL™ II

BISFIL II is a self-cured, highly filled, radiopaque composite recommended for posterior restorations. The high filler concentration in BISFIL II (80%) results in improved abrasion resistance as well as high tensile and compressive strength. These properties are essential for composites to function effectively in the posterior segments. Optimum results require that BISFIL II be used in conjunction with a high quality dentin-enamel adhesive system such as ALL-BOND® 2 or ONE-STEP™.

Leading clinicians (Dr. John Kanca, Middlebury, CT) have recommend that BISFIL II be used as the base increment, to replace dentin, underneath a light - cure restorative in the "directed shrinkage" technique. Being self - cured, BISFIL II tends to cure towards the warmth of the tooth, rather than towards a light source, to prevent development of a marginal gap.

DESCRIPTION OF THE APPLICANT COMPOSITE

BISFIL 2B (directed shrinkage composite) is a self-cure, base increment, radiopaque composite recommended for the "directed shrinkage" posterior composite technique suggested by Dr. Raymond Bertolotti.

BISFIL 2B begins curing adjacent to the naturally warmer surfaces of the dentin in the directed shrinkage technique. This is in contrast to light-cure composites which tend to begin curing towards the light source. Since all composites shrink on curing, the net effect of the directed shrinkage technique is to direct polymerization toward the tooth to help prevent formation of a marginal gap.

BISFIL 2B is a naturally sticky, syringable composite that is intended to be overlaid with a condensable light-cure posterior composite such as AELITEFIL™ or BISFIL P™. BISFIL 2B is intended to be used with ALL-BOND 2® or ONE-STEP™, or similar universal dental adhesive system.

INTENDED USES OF APPLICANT COMPOSITE

BISFIL 2B is indicated for use as a base increment posterior composite. It is intended to be used with ALL-BOND 2® or ONE-STEP™, or similar universal dental adhesive system. BISFIL 2B will bond to the enamel / dentin bonding system such as ONE-STEP. BISFIL 2B is intended to be covered by a high quality light-cure composite.

SCIENTIFIC CONCEPTS and SIGNIFICANT PERFORMANCE CHARACTERISTICS

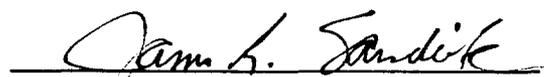
There has been a great deal of discussion in the dental research literature over the effect of polymerization shrinkage on the quality of a dental restoration. On the one hand, older systems did not bond to tooth structure so shrinkage simply resulted in gap formation between the tooth and restoration resulting in leakage and recurrent caries. Modern materials, on the other hand, bond well to tooth structure. During shrinkage, pain may occur due to stress placed on the tooth, a cusp may actually fracture because of the stress, or the bond may break resulting in leakage.

In the absence of a true non-shrinking composite, several tricks have been used to reduce or overcome the effects of polymerization shrinkage. One of these is the "directed shrinkage technique" proposed by Dr. Raymond Bertolotti (see references). Bertolotti proposed that a self-cure composite will produce less shrinkage stress because, during curing, the stress is relaxed in the presence of uncured material. As the material cures more of the paste is converted to solid until such time as no fluid phase is present to accommodate the shrinkage, at which time the stress accumulates quickly. Conversely, a light-cure composite cures very quickly and there is very little time for the paste to accommodate shrinkage.

BISFIL 2B overcomes the above problems because of its higher resin content and its ability to flow while in the paste/fluid state during the early stages of curing. In addition, Dr. Bertolotti hypothesized that the warmer surface of the tooth will tend to polymerize the material in contact with it. This effectively causes shrinkage to occur toward rather than away from the tooth as might occur with a light-cure material. This hypothesis has been tested by Garberoglio (see References, #7) and others and found plausible.

The chemical composition of BISFIL 2B and BISFIL II are very similar. Both are silica and glass filled dimethacrylate composites. The resin compositions of both products are nearly identical with BISFIL 2B having somewhat less filler and lower viscosity.

The non-clinical tests used for this submission are similar to those specified in ISO 4049 and American Dental Association Specification #27. Diametral tensile testing is an accepted method to characterize the tensile strength of relatively brittle materials and the flexural modulus has become important recently in characterizing the strength in three point loading.



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