

K964867

**parkell**

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510(k) SUMMARY

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Contact: Same as above.

Date of Submission: November 25, 1996

Trade Name: Hybrid Composite Resin

Common Name: Hybrid Composite Material

Classification Name: Tooth Shade Resin Material (21 CFR §872.3690)

Equivalence: PRISMA-FIL; ESTILUX POSTERIOR XR; BISFIL-1;  
OCCLUSIN; HERCULITE; P-50; PERTAC HYBRID;  
Z100; TETRIC

Description and Intended Use: May be described as a radiopaque, light-cured, hybrid composite resin for use as a tooth colored dental restorative in Class I, II, III, IV and V cavities. It is contoured and polished using currently available finishing diamonds, finishing burs, discs, and polishing pastes. When used as indicated, the material is recommended for restoring proper form and function of restored teeth.

The above-cited material contains materials that are common in dental resins and pose no health hazard when used according to directions. Use of composite resins may be contra-indicated in persons with known acrylate allergies and/or hypersensitivities. The material is polymerizable with currently available visible light curing devices.