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DENTSPLY

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510(k) SUMMARY

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DATE PREPARED: April 18, 1996

TRADE OR PROPRIETARY NAME: AH[®] PLUS[™] ROOT CANAL SEALER

COMMON OR USUAL NAME: Root Canal Sealer

CLASSIFICATION NAME: Root Canal Filling Resin 21 CFR, 872.3820

LEGALLY MARKETED DEVICE: AH26[®] Root Canal Sealer Pre-1976 Device

DEVICE DESCRIPTION: AH[®] PLUS[™] Root Canal Sealer is a two-component paste: paste root canal sealer based on epoxy-amine resin chemistry. This easy-to-mix sealer adapts closely to the walls of the prepared root canal and provides outstanding long-term dimensional stability with minimal shrinkage upon setting.

The final product consists of two components, the epoxy resin paste (Paste A) and the amine-containing paste (Paste B) portions which are mixed prior to insertion into the root canal.

AH[®] PLUS[™] Root Canal Sealer and AH26[®] Root Canal Sealer are both two-component systems that react via an epoxide/amine chemical reaction to cause setting. They are both used in conjunction with the same auxiliary materials in the root canal (e.g., gutta percha points).

The physical properties of AH[®] PLUS[™] Root Canal Sealer meet or exceed those standards found in ISO Specification 6876 and ADA Specification 57. AH[®] PLUS[™] Root Canal Sealer and AH26[®] Root Canal Sealer are comparable in setting time, flow, shrinkage, and microleakage physical property values.

INTENDED USE: AH[®] PLUS[™] Root Canal Sealer is used for permanent sealing of root canals following established endodontic procedures. The predicate device, AH26[®] Root Canal Sealer has the same intended use.

510(k) SUMMARY (cont'd.)

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TECHNOLOGICAL CHARACTERISTICS: The components of AH[®] PLUS[™] Root Canal Sealer are either found in other DENTSPLY legally marketed predicate devices or their safety is documented in Material Safety Data Sheets.

AH[®] PLUS[™] Root Canal Sealer has undergone extensive pre-clinical testing.

Paste A, the amines contained in Paste B, and the mixed cured sealer were evaluated using the Ames Mutagenicity Test and found to be non-mutagenic.

The resins contained in Paste A were found to have an LD₅₀ in rats of >5000 mg/kg in studies reported in MSDSs. Paste B was evaluated for Acute Oral Toxicity in rats and found to be non-toxic. The mixed cured sealer was evaluated using the Growth Inhibition Test and found to be non-cytotoxic.

The mixed, cured sealer was evaluated in guinea pigs for its sensitization potential and found to be a weak sensitizer according to ISO 10993-10 and a non-sensitizer according to OECD guidelines.

Implantation tests in rabbits on the mixed sealer resulted in no macroscopic visible response and a moderate degree of microscopic response. There was no other evidence of an irritant effect of the sealer.

CONCLUSION

The results of our testing show that, the fact that AH[®] PLUS[™] Root Canal Sealer has different technological characteristics than the predicate device, does not raise different questions of safety and efficacy.

We believe this is supported by the ingredient toxicity testing, the performance data, and the final product testing of AH[®] PLUS[™] Root Canal Sealer.