

SS White Manufacturing

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K964179
JAN. 9, 1997

PREMARKET NOTIFICATION**510(k) SUMMARY**

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DATE PREPARED: 9th October, 1996



PREMARKET NOTIFICATION**510(k) SUMMARY (continued)**

TRADE NAMES: Super-Dent Etching Gel
Super-Dent Micro-Etch Gel
Super-Dent Etching Gel Syringe Tips

COMMON NAME: Phosphoric acid etching gel

CLASSIFICATION NAME: Dental cement accessory, phosphoric acid etching gel

EQUIVALENT TO: Zenith 40% Phosphoric Acid Gel
510(k) No. K890464

DESCRIPTION:

These materials consist of a gel containing ortho-phosphoric acid.

INTENDED USE:

These materials are intended for use in preparation of tooth material prior to restoration by etching of the surface.

TECHNOLOGICAL CHARACTERISTICS:

Both devices are aqueous gels containing a nominal 40% ortho-phosphoric acid and delivered directly to the restoration site from a syringe via a hollow applicator. Both devices are coloured for visibility in contrast with tooth material. They are sufficiently viscous to remain where placed and avoid potentially harmful contamination of more sensitive oral tissues. Both devices wash readily from the site when etching is complete.

The subject device is intentionally more viscous than the predicate device to improve adhesion after placement.

PREMARKET NOTIFICATION**510(k) SUMMARY (continued)****NON-CLINICAL DATA:**

Non-clinical testing includes tests for pH, acid content, adhesion and water washability.

The tests indicate results for pH and acid content which are comparable within formulation and experimental accuracy.

The test for adhesion indicates better adhesion of the *subject device*. The device is intentionally more viscous than the predicate device to improve adhesion after placement.

The test for water washability indicates marginally easier washability for the *predicate device*. This is a direct result of the intentionally increased viscosity (and adhesion) of the subject device. The washability of the subject device is satisfactory on consideration of the method of removal.

CLINICAL DATA:

There is none applicable

CONCLUSIONS:

The data summarised above indicates that the subject device is substantially equivalent to the predicate device.

Any differences in performance are a result of improvements designed to render the product safer and more effective in clinical use.