

K972369

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510 (k) Summary

Statement of Safety and Effectiveness

AUG 15 1997

Kerr Modified Sealapex Root Canal Sealer

BACKGROUND

Sealapex is a root canal sealing material which has been used successfully by the dental profession since 1984. The original Sealapex formulation received market clearance from the Food and Drug Administration in July of 1984 (510 (k) Reference Number K841910). Another 510 (k) application was submitted in September, 1994 for minor formulation changes to extend the working time (510 (k) Reference Number K944480). This submission addresses two anticipated formulation modifications which will, when implemented, make the manufacturing process for synthesizing one of the polymeric resins safer to the employees, and increase the radiopacity by fifty per cent.

Current Sealapex formulations utilize Poly(methylene methyl salicylate) resin in the catalyst paste component. It is synthesized in-house using formaldehyde as one of the reactants. Formaldehyde is considered to be carcinogenic and presents a serious hazard in the workplace. If Neopentyl glycol disalicylate/ trimethylol propane trisalicylate (NPG-TMP salicylate) resin is substituted for the current resin, the use of formaldehyde is eliminated. The second modification consists of the addition of bismuth trioxide to the catalyst component to increase the radiopacity of the mixed sealant.

Modified Sealapex

The two formulation changes described above do not alter the safety and efficacy of the product to the extent that the new formulation is not significantly equivalent to products currently on the market and under the jurisdiction of FDA. This is demonstrated below:

Change Number 1: Substitution of poly(methylene methyl salicylate) resin with NPG-TMP Salicylate resin. NPG-TMP Salicylate has been used successfully and safely since 1996 in Kerr's Life Cavity Base/Liner (510 (k) Reference Number K961708). And, in fact, that resin change was made for exactly the same reasons described in this submission and was based on extensive animal histopathology studies which demonstrated both the biocompatibility of the resin and the ability of the calcium hydroxide ingredient to stimulate the formation of hard tissue both in the periapical area and along the canal walls as well.

Change Number 2: The addition of bismuth trioxide to increase the radiopacity of the set sealant. Bismuth trioxide has been used previously in root canal sealers. Procosol, Grossman's Sealer, Wach's Paste, Diaket and AH-26 all use bismuth compounds as radiopaquing agents. In the case of AH-26, it has 60 % by weight bismuth trioxide. All of these products are currently on the market under the jurisdiction of FDA.

A table of comparative ingredient lists for the modified Sealapex formulation along with predicate device compositions, where known is included elsewhere in this submission in order to contrast and compare the various devices.

Safety

The safety of the modified Sealapex formulation has been demonstrated in extensive animal histopathology studies. Copies of reports of these studies are included elsewhere in this submission.

Efficacy

The effectiveness of the modified Sealapex formulation has been demonstrated by comparison testing of several predicate devices to the requirements of ISO International Standard 6876 for Dental root canal sealing materials. A copy of this standard as well as a table of comparative results can be found elsewhere in this submission.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William R. Pike
Regulatory Affairs Specialist
Sybron Dental Specialities, Incorporated
±717 W. Collins Avenue
Orange, California 92667

AUG 15 1997

Re: K972369
Trade Name: Sealapex
Regulatory Class: II
Product Code: KIF
Dated: June 6, 1997
Received: June 25, 1997

Dear Mr. Pike:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

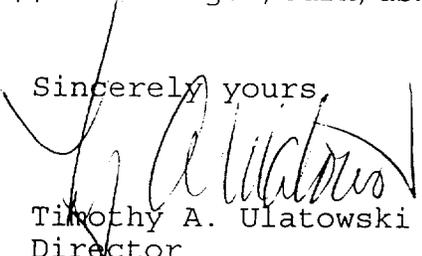
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number : _____

Device Name : Kerr Modified Sealapex Root Canal Sealer

Indications For Use : Kerr Modified Sealapex Root Canal Sealer is a two- paste, non-eugenol, radiopaque, calcium hydroxide polymeric resin root canal filling material. It is intended for use as a root canal sealer to be used in conjunction with gutta percha or silver endodontic points.



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number ICA 72369

Prescription: Use _____
(Per 21 CFR 801.109)