

K973539

Section 9  
510(k) Summary

OCT 30 1997

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. § 807.92.

1. The submitter of this premarket notification is:  
James Delaney, Associate  
EXPERTech Associates, Inc.  
100 Main Street, Suite 120  
Concord, MA 01742-5307  
Tel.: (508) 371 - 0066  
Fax : (508) 371 - 1676

This summary was prepared on August 29, 1997.

2. The name of this device is Roeko Calcium Hydroxide Points. Its common name is Calcium Hydroxide Points, and its classification name is Calcium Hydroxide Cavity Liner.

3. The Roeko Calcium Hydroxide Points are substantially equivalent to TempCanal™ manufactured by Pulpdent Corporation.

4. The Roeko Calcium Hydroxide Points are deposit preparations which release calcium hydroxide from a gutta percha matrix. The device consists of calcium hydroxide, gutta percha, barium sulfate, stearic acid, and colorants.

5. The device is intended for temporary filling, and disinfection of root canals between endodontic visits following pulp removal.

6. The technical characteristics are similar to those found with the predicate device where a root canal is temporarily filled with calcium hydroxide. In the Roeko device, calcium hydroxide powder is delivered from a gutta percha matrix inserted into the canal. In the predicate device, calcium hydroxide is delivered as an aqueous suspension by dispensing it into the canal through a syringe.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. James Delaney  
Associate  
Roeko USA, Incorporated  
C/O Expertech Associate, Incorporated  
100 Main Street, Suite 120  
Concord, Massachusetts 01742

OCT 30 1997

Re: K973539  
Trade Name: Roeko Calcium Hydroxide Points  
Regulatory Class: II  
Product Code: EJK  
Dated: September 15, 1997  
Received: September 18, 1997

Dear Mr. Delaney:

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

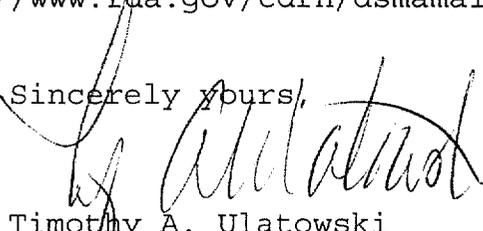
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 (if known): K973539

Device Name: Roeko Calcium Hydroxide Points

Indications For Use: For calcium hydroxide root canal therapy either prior to or after root canal preparation; for emergency root canal treatment; for treatment of root resorptions; and for early childhood trauma.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Susan Ruzar*

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

510(k) Number Ka 73539

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_