

K983037

Section 9

510 (k) Summary

This summary of 510 (k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Device 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  
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This summary was prepared on August 27, 1998

2. The name of this device is Root canal filling material. Its common name is Roeko Seal and its classification is root canal filling material.

3. Roeko Seal is substantially equivalent to Lee Endo-Fill manufactured by Lee Pharmaceuticals.

4. Roeko Seal is a permanent root canal filling material, which is silicone based (Polydimethylsiloxane) and consists additionally of zircon dioxide, paraffin-based oil silicone oil, hexachloroplatinic acid and silicic acid.

5. The technical characteristics are similar to those found with the predicate device Lee Endo-Fill, which is also silicone based. Dimensional stability, flow, and biocompatibility are very high for both materials. Differences are only in the polymerization process and the method of mixing/application.



OCT 20 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Roeko GmbH & Company  
C/O Mr. James Delaney  
Associate  
EXPERTech Associates, Incorporated  
100 Main Street, Suite 120  
Concord, Massachusetts 01742-5307

Re: K983037  
Trade Name: Roeko Seal  
Regulatory Class: II  
Product Code: KIF  
Dated: August 28, 1998  
Received: August 31, 1998

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.

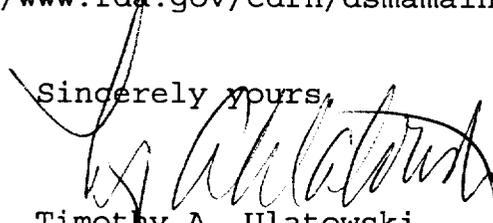
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 through 542 of

Page 2 - Mr. Delaney

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) 594-4692. 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): K983037

Device Name: Roeko Seal

Indications for Use: The Roeko Seal root canal sealer is indicated in patients for permanent obturations of root canal after vital extirpation or after treatment of pulpal gangrene and temporary filling.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gerald Stuppa  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K983037

Prescription Use   
(Per 21 CFR 801.109)

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

(Optional Format 1-2-96)