

K972747

Summary of Safety and Effectiveness

JAN - 9 1998

510(k) Submission K97 2747

Propper BI-O.K.<sup>TM</sup> EO Gas Biological Test-Pak

General Information:

Submitters Name/Address:

Propper Manufacturing Co., Inc.  
36-04 Skillman Avenue  
Long Island City, New York 11101  
Attn: John D. Dyckman Ph.D.

Common Name of the Device:

Biological/Chemical Indicator

Trade Name of the Device:

BI-O.K.<sup>TM</sup> Ethylene Oxide Gas Biological Test-Pak

Classification Information:

Class II

Sterilization Process Indicator

Indications for Use:

The Prior BI O.K.<sup>TM</sup> EO Gas Biological Test-Pak is intended for use as a disposable device for the biological monitoring of ethylene oxide sterilizers in health care facilities. Its construction closely duplicates that described for such testing by AAMI/ANSI ST41-1992.

### **Device Description:**

The BI-O.K. EO Gas Biological Test-Pak consists of a BI-O.K. EO Gas Biological Indicator placed inside a plastic syringe. The syringe along with a Record Card and absorbent towel are enclosed in a paper/plastic peel pouch suitable for use in ethylene oxide sterilizers.

### **Substantial Equivalence:**

The Proper BI-O.K. EO Gas Biological Test-Pak is substantially equivalent to the standard pack described by AAMI as well as commercially available test packs marketed by 3M and ATI which employ biological indicators for monitoring ethylene oxide sterilization in health care facilities.

### **Performance studies:**

The Proper BI-O.K. EO Gas Biological Test-Pak was tested in-house in a Joslyn BIER vessel to determine the performance characteristics of the system under controlled, reproducible conditions consisting of 60% RH, 600 mg/L ethylene oxide and 54.4°C. The results obtained are similar to those reported for similar devices.

### **Conclusion:**

Based upon the indications for use, construction, and performance, the Proper BI-O.K. EO Gas Biological Test-Pak has been shown to be suitable for its intended use.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN - 9 1998

John D. Dyckman, Ph.D.  
Director, Product Research  
Propper Manufacturing Company, Incorporated  
36-04 Skillman Avenue  
Long Island City, New York 11101

Re: K972747  
Trade Name: BI-O.K.™ EO Gas Biological Test-Pak  
(269305,269310,269320)  
Regulatory Class: II  
Product Code: FRC  
Dated: November 17, 1997  
Received: November 20, 1997

Dear Dr. Dyekman:

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.

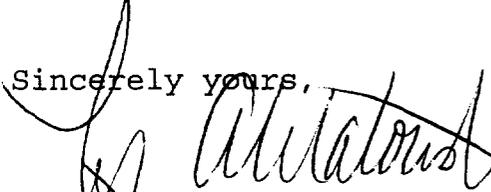
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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 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): \_\_\_\_\_

Device Name: \_\_\_\_\_

Indications For Use:

**INDICATIONS FOR USE**

The Proper BI-O.K. Gas Biological Test Pack is indicated for use as an aid or adjunct for use in biological monitoring of ethylene oxide sterilizers only. Its performance was verified versus the standard AAMI pack under the conditions of 600 mg/L ethylene oxide, 60% RH, 54.4 C in a Jostyn BIER vessel using a 10% ethylene oxide, 90% HCFC gas mixture.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Chin S. Lin*

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

510(k) Number         K972747        

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

OR

Over-The-Counter Use   X  

(Optional Format 1-2-96)

