

JUL 12 1999

**SUMMARY OF SAFETY AND EFFECTIVENESS**

510 (k) Submission K99 1276

Propper PASS/FAIL Challenge Pack

General Information:

Submitter's Name/Address:

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

Common Name of the Device:

Biological/Chemical Indicator

Trade Name of the Device:

PASS/FAIL Challenge Pack

Classification Information:

Class II, Sterilization Process Indicator

Indications for Use:

The Propper PASS/FAIL Challenge Pack is indicated for use in testing gravity displacement steam sterilizers at 121°C and prevacuum steam sterilizers at 134°C.

Device Description:

The PASS/FAIL Challenge Pack consists of a Propper Vapor Line steam sterilization integrator placed inside a test pack similar in construction to the Propper BI- O.K.™ steam sterilization test pack.

Substantial Equivalence:

The PASS/FAIL Challenge Pack consists of a Propper Vapor Line steam sterilization integrator placed inside a test pack similar in construction to the Propper BI- O.K.™ steam sterilization test pack.

Substantial Equivalence:

The Propper PASS/FAIL Challenge Pack is substantially equivalent to several biological test packs marketed for testing steam sterilization at 121° C in gravity displacement sterilizers or at 132-134°C in prevacuum sterilizers. Composite results from comparative testing of these products are given in the two figures which accompany this summary.

Conclusion:

Based upon the indications for use and documented performance, the Propper PASS/FAIL Challenge Pack has been shown to be both safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 12 1999

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

Re: K991276  
Trade Name: PASS/FAIL™ Challenge Pack  
Regulatory Class: II  
Product Code: JOJ  
Dated: May 20, 1999  
Received: May 21, 1999

Dear Dr. Dyckman:

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 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.

Page 2 - Dr. Dyckman

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) 594-4692. 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,



for 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: PASS/FAIL Challenge Pack

Indications For Use:

The Propper PASS/FAIL Challenge Pack is indicated for use in testing gravity displacement steam sterilizers at 121°C and prevacuum steam sterilizers at 134°C.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

OR

Over-The-Counter Use X

Chun S. Lin  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K991276

(Optional Format 1-2-96)