AUG 17 2004

510(k) SUMMARY

Propper Vapor Line PCD
Steam Sterilization Process Challenge Test
510(k) Number: **K031152**

Submitter Information: Propper Manufacturing Co., Inc.
36-04 Skillman Avenue
Long Island City, NY 11101
Attn: Frank E. Platko, Ph.D.
Telephone: (718) 392-6650 Ext. 264

Device Name: (Trade:) Propper Vapor Line PCD Steam Sterilization Process Challenge Test
(Common:) Steam Chemical Indicator
(Classification:) Physical/Chemical Sterilization Process Indicator

Substantial Equivalence Device: Propper Bio-Challenge Test-Pak

Device Description: Propper Vapor Line PCD is a process challenge test device for use in pre-vacuum steam sterilization processes at 273.2°F/134°C. It consists of a capsule with a removable cap and sample holder to permit the positioning and removal of the Propper Vapor Line Integrator. One end of the capsule is connected to a lumen. During the sterilization cycle, the open end of the lumen permits residual air to exit and steam to enter the capsule The integrator display will indicate whether or not sterilization conditions were attained inside the metal capsule.

Intended Use Of Device: The Propper Vapor Line PCD is indicated for use in routine challenge testing steam sterilizers in pre-vacuum cycles operating at 273.2°F/134°C.

Technological Characteristics: The Propper Vapor Line PCD and Propper Bio-Challenge Test-Pak are both Steam Process Challenge test devices designed for use in steam sterilization processes. They are similar in function but differ in design and construction.

The challenge to steam penetration presented by the Propper Vapor Line PCD is controlled by the length, bore and configuration of the lumen which is the only opening into the capsule. Whereas, the corresponding

510(k) Summary---continued

challenge by the Propper Bio-Challenge Test-Pak is determined by a steam-resistant paper load and a rate controlling barrier film.

Nonclinical Tests:

The safety and effectiveness of the Propper Vapor Line PCD Steam Sterilization Process Challenge Test were determined by comparing the performance characteristics of this device directly to that of the Propper Bio-Challenge Test-Pak in side-by-side testing in a steam sterilizer.

Before each test cycle, a Propper Vapor Line Integrator was placed into the slot of the PCD sample holder which was then inserted into the body of the metal capsule and secured in position with the screw cap. The PCD device was placed inside the sterilizer chamber on the lower rack over the drain, side-by-side with two Propper Bio-Challenge Test-Paks. One pack contained a Duo-Spore indicator and the other a BI-OK indicator. Then, a conventional 4-pulse pre-vacuum steam sterilization cycle was run. Cycle tests were run at 273.2°F/134°C for different exposure times.

After each sterilization cycle, the Vapor Line integrator was retrieved and examined to determine the "PASS" or "FAIL" reading. The Duo-Spore strip was aseptically removed from its glassine envelope, transferred to trypticase soy broth and incubated at 56°C. The spore strip was examined for growth on a daily basis for seven days. The BI-OK vial was activated, incubated at 56°C for 48 hours and then examined for growth. A second sterilizer study was conducted to establish multiple device equivalency. Complete test results appear in tabular form at the end of this summary

Test Conclusions:

The Propper Vapor Line PCD is a highly reproducible challenge test. It will not indicate acceptable "PASS" results until after complete spore death has occurred. Based on the performance data, the test is safe and effective for its intended use. It is substantially equivalent in performance to commercial biological challenge tests used in pre-vacuum steam sterilizer cycle testing.

VAPOR LINE PCD vs BIO-CHALLENGE TEST-PAK
Exposure Time vs % Fail/Survival

273.2F(134C)						
Exposure Time (min.)	**0.25**	**0.60**	**1.00**	**1.50**	**1.75**	**2.00**
% Survived (Duo-Spore)*	0	0	0	0	0	0
% Survived (BI-O.K.)	80	40	0	0	0	0
% Fail (Propper Vapor Line PCD)	100	100	100	100	15	0
Total No. of Tests	5	20	20	5	20	20

* Complete spore death occurred prior to 0.25 minutes exposure

PROPPER VAPOR LINE PCD
MULTIPLE DEVICE EQUIVALENCY STUDY

Temperature @ 273.2F/134C

Exposure Time (min.)	**1.50**	**1.75**	**2.00**
	Fail/Total	Fail/Total	Fail/Total
PCD 1*	1/1	3/6	0/6
PCD 2	1/1	4/6	0/6
PCD 3	1/1	3/6	0/6
PCD 4	1/1	2/6	0/6
PCD 5	1/1	2/6	0/6
% FAIL (Vapor Line PCD)	100	47	0
Total Number of Tests	5	30	30

* PCD # 1 also used in comparative testing vs Bio-Challenge Test Pak

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2004

Dr. John D. Dyckman
Vice President, Research and Development
Propper Manufacturing Company, Incorporated
36-04 Skillman Avenue
Long Island City, New York 11101

Re: K031152
Trade/Device Name: Propper Vapor Line PCD Steam Sterilization Process Challenge Test
Regulation Number: 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 28, 2004
Received: June 2, 2004

Dear Dr. Dyckman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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.

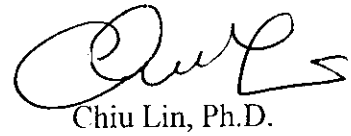
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031152

Device Name: Propper Vapor Line PCD Steam Sterilization Process Challenge Test

Indications For Use:

The PROPPER VAPOR LINE PCD is indicated for use as a routine process challenge test for steam sterilizers in pre-vacuum cycles at 273.2°F/134°C.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K031152

Prescription Use_____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)

(Optional Format 1-2-96)