

MAY 20 1999

510(K) SUMMARY

- [2] Roger L. Goodman, D.D.S., P.C.                      October 1, 1997  
200 Temple Street  
Mason, Michigan 48854-1837    (517) 676-5200    FAX: (517)676-5442  
Contact Person: Roger L. Goodman
- [3] Name of device: Vapo Solution™ for use only in Chemiclave Sterilizers  
Trade name: Vapo Solution™ for use only in Chemiclave Sterilizers  
Common name: Alcohol Solution for use only in Chemiclave Sterilizers  
Classification name: 21 CFR 880.6890  
Product code: 80MLR  
Device classification: Class II
- [4] Equivalence to: MDT Harvey Vapo-Steril® solution for use only in Harvey Chemiclave® sterilizers
- [5] Description of device: A specific solution of various alcohols, acetone, ketone, formaldehyde, and distilled water for use only in MDT Harvey Chemiclave® sterilizers.
- [6] Intended use of Device: Vapo Solution™, a generic substitute for Harvey Vapo-Steril® solution, is used in sterilizing dental and surgical instruments in MDT Harvey Chemiclave® sterilizers. The unsaturated chemical vapor is analogous to steam vapor in autoclave sterilizers.
- [7] Technological characteristics: Vapo Solution™ and Harvey Vapo-Steril® solution have identical active ingredients of 72.38% ethyl alcohol and 0.23% formaldehyde; and substantially the same inert ingredients of 27.39%
- [8] Performance Data: 4,000 independent tests were performed using 'fresh' solutions; 600 additional tests using one-year old solutions; 600 tests using two-year old solutions.  

	Model 5000-6"		Model 5500-8"		Model 6000-10"	
	tests completed	+growth	tests completed	+growth	tests completed	+growth
Vapo Solution™	680	219	650	119	680	261
Vapo-Steril solution®	670	222	640	183	680	328

Statistical analysis indicates that the Vapo Solution™ is equal to or better than the predicate Vapo-Steril® solution in killing spore strips of *Bacillus stearothermophilus* when tested according to method used for such testing.
- [9] Conclusion: From non-clinical tests, the Model 5000 shows no significant difference in survivors for the two solutions; the Models 5500 and 6000 show a significant difference in survivors at shorter cycle times (Vapo Solution™ has fewer survivors), but no significant difference at longer cycle times. The two solutions are substantially the same in efficacy.  
One-year old solution: Same comparative results.  
Two-year old solution: Same comparative results.
- [10] Toxicology: A study conducted in dental offices using an analogous alcohol solution containing 0.23% formaldehyde reported the following: 15 min STEL ave. 0.81 ppm (OSHA 2.0 ppm); 8-hour average 0.029 ppm (OSHA TWA 1.0 ppm). 29 CFR 1910.1048 >0.1 ppm considered a Health Hazard.

®MDT, Harvey, and Chemiclave are registered trademarks of MDT Corp.  
 ®Vapo-Steril is a registered trademark of MDT Biologic Company.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."



MAY 20 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Roger L. Goodman, D.D.S., P.C.  
200 Temple Street  
Mason, MI 48854

Re: K984270

Trade Name: Vapo-Solution for use in MDT Harvey Chemiclave Sterilizers  
Models 5000, 5500 and 6000

Regulatory Class: Unclassified

Product Code: MED

Dated: November 25, 1998

Received: November 30, 1998

Dear Dr. Goodman:

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 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). 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.

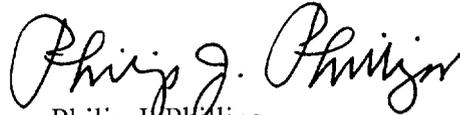
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Dr. Goodman

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" (21CFR 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/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Philip J. Phillips". The signature is written in a cursive style with a large, prominent "P" at the beginning.

Philip J. Phillips  
Deputy Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known) K984270

Device Name: VAPO SOLUTION™

**Indications for Use:**

Vapo Solution™ is an alcohol solution intended to be used only in Harvey Chemiclave sterilizers to sterilize medical and dental surgical instruments and equipment. Vapo Solution™ is intended to be a direct substitute for Vapo-Steril®. Vapo Solution™ is recommended for use in the following Chemiclave models: 4000, 5000, 5500, 6000, and models covered under K924380 and K943654.

Vapo Solution™ is compatible with Chemiclave cycle parameters as follows:

Model 4000, 5000, 5500, 6000, EM5000, EM5500, and EM6000

- Operating pressure: 20-40 psi (1.41 - 2.82 kg/cm<sup>2</sup>)
- Operating Temperature: 132 ± 2 °C (270 ± 5 °F)
- Maximum load: Bagged instruments:
  - 6" Chamber (models 4000, 5000, EM5000) 0.6 Kg (1.3 lbs)
  - 8" Chamber (models 5500, EM5500) 1.2 Kg (2.6 lbs)
  - 10" Chamber (models 6000, EM6000) 2.4 Kg (5.3 lbs)
- Maximum load: Unwrapped instruments:
  - 6" Chamber (models 4000, 5000, EM5000) 0.75 Kg (1.7 lbs)
  - 8" Chamber (models 5500, EM5500) 1.4 Kg (3.1 lbs)
  - 10" Chamber (models 6000, EM6000) 2.8 Kg (6.2 lbs)

Model 7000 and 8000

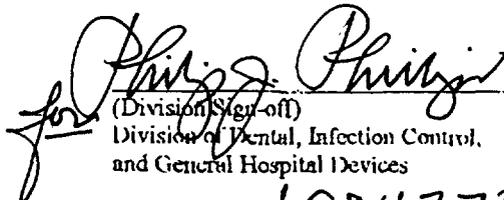
- Operating pressure: approximately 25 psi
- Operating Temperature: 132 ± 2 °C (270 ± 5 °F)
- Maximum load: Bagged instruments:
  - 8" Chamber (model 7000) 1.2 Kg (2.6 lbs)
  - 10" Chamber (model 8000) 2.4 Kg (5.3 lbs)
- Maximum load: Unwrapped instruments:
  - 8" Chamber (model 7000) 1.4 Kg (3.1 lbs)
  - 10" Chamber (model 8000) 2.8 Kg (6.2 lbs)

Vapo Solution™ is compatible with but not limited to the following instruments and material types:

- Surgical and cutting instruments, handpieces, and similar items
- Plastics that can tolerate in excess of 132 °C: i.e. Polysulfone, Phenolic, Nylon, Teflon, Polyethylene, Polyester, Polypropylene. Note: Polycarbonate is not chemically compatible.
- Rubber components made of Silicone, Fluorosilicone

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

Concurrence of CDRL Office of Device Evaluation (ODE)

  
for (Division Sign-off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K984270

510(k) Number (if known) K984270

Device Name: VAPO SOLUTION™

Indications for Use:

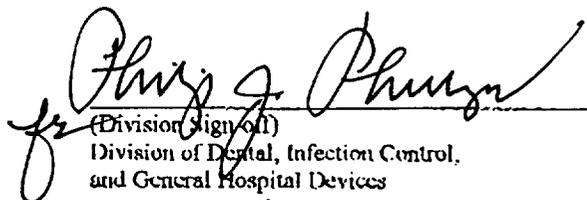
Vapo Solution™ is not compatible with the following materials:

- Linen, textiles or fabrics - These are incompatible with the chemical vapor process.
- Liquids and agars - These are incompatible with high temperature processing (132°C).
- Items contained in tightly woven packs or wraps, or sealed containers - These cause poor vapor penetration.
- Plastics which cannot tolerate temperatures in excess of 132°C.
- Polycarbonate - Chemically incompatible.
- Nylon tubing and bags - Inhibits penetration of chemical vapors.

Vapo Solution™ is not recommended for use for "flash" sterilization cycles.

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

Concurrence of CDRII, Office of Device Evaluation (ODE)

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

510(k) Number K984270