

K970726

**ATTACHMENT 7**

**510(k) Summary**

**Cottrell, Ltd.**

JUN 16 1998

**Vapocide™ Liquid Chemical Sterilant**

**1. Sponsor/Applicant Name**

Cottrell, Ltd.  
7399 South Tucson Way  
Englewood, CO 80112  
Telephone: (303) 799-9401  
Facsimile: (303) 799-9408

**Contact Person**

Mr. John Scoville  
Director of Regulatory Affairs and Quality Assurance

**Date of Summary Preparation**

February 27, 1997

**2. Device Name**

Proprietary Name: Vapocide™  
Common/Usual Name: Liquid Chemical Sterilant  
Classification Name: Liquid Chemical Sterilant

**3. Identification of the predicate or legally marketed device(s) to which equivalence is being claimed**

The Cottrell, Ltd. Vapocide™ is substantially equivalent to Vapo-Steril which is manufactured by MDT Biologic Company. The Vapo-Steril solution has been in commercial distribution for as long as the Harvey Chemiclave sterilizer. They are preamendments devices and also are covered under several 510(k) premarket notifications such as K924380 MDT-Harvey Model 7000 and 8000CHE, and K943654- Harvey Chemiclave EC 5000, 5500, and 6000 MDT Biologic.

**4. Device Description**

Vapocide™ is a liquid sterilant solution designed for use in Harvey Chemiclave sterilizers only. Vapocide™ and the Harvey Chemiclave function as a system to sterilize medical and dental surgical instruments and equipment. Vapocide™ is a sterilant solution intended to be used in the Harvey Chemiclave which is an unsaturated chemical vapor sterilizer. Unsaturated chemical vapor sterilizers function by using heat, water, and chemical synergism to sterilize medical and dental equipment. Vapocide™ is made of formaldehyde and ethanol. This formulation when heated under pressure, results in a relatively unsaturated and totally effective sterilization vapor which does not have deleterious effects on metal surfaces.

**5. Intended Use**

Vapocide™ is a sterilant solution intended to be used in the Harvey Chemiclave Sterilizer to sterilize medical and dental surgical instruments and equipment.

**6. A statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device(s) cited**

Vapocide™ and the predicate Vapo-Steril liquid chemical sterilants are similar with respect to shelf-life, appearance, and viscosity in that they both have a 2 year shelf life and are clear, colorless liquids. Vapocide™ and predicate Vapo-Steril liquid chemical sterilants are similar in chemical properties in that the primary active ingredient in both solution is formaldehyde with ethanol acting synergistically to achieve sterilization. The concentration of formaldehyde in both solutions is 0.23%. Vapocide™ and the predicate Vapo-Steril solutions are similar in microbiology claims in that they are sterilants and therefore sporicidal.

**7. Performance Testing**

**Performance Testing**

Testing was performed to determine the effectiveness of Vapocide™ when used as a liquid chemical sterilant in the Harvey Chemiclave Sterilizer. The tests and results are summarized below:

**8. Conclusion.** Based upon all testing summarized above, Vapocide™ is substantially equivalent to Vapo-Steril, which was on the market prior to May, 1976, for use in all Chemiclave models.

**Comparative testing using Vapocide™ and Vapo-Steril:**

Comparison Testing was performed on Vapocide™ and Vapo-Steril using a modified AOAC Sporicidal Test Protocol.

**Sporicidal Testing:**

AOAC Sporicidal testing was performed by Sterilization Technical Services. This testing used *Bacillus subtilis* and *Clostridium sporogenes* to determine the sporicidal effectiveness of Vapocide™.

**Simulated Use Testing:**

Simulated use testing was performed using inoculated dental Handpieces packaged in sterilization pouches processed in the Harvey Chemiclave 8000 sterilizer. The objective of this study was to determine if *Bacillus stearothermophilus* spores placed on the turbines inside of dental Handpieces in a worse case load are killed using the Harvey Chemiclave and Vapocide™ liquid chemical sterilant.

**Comparison Test for Effectiveness of Vapocide™ and Vapo-Steril:**

The purpose of this study was to determine the relative efficacy of Vapocide™ under typical use conditions, i.e. instruments, packaging, loading, sterilization process conditions, etc. as well as under half cycle conditions.

**Material Compatibility of Vapocide™:**

The purpose of this study was to demonstrate material compatibility of Vapocide™ under repeated processing of various medical and dental instruments, i.e., orthopedic pliers, hand instruments, carbon steel burrs, high speed Handpieces, plastic resin cassettes. Each of the processed instruments were processed repeatedly using the Harvey Chemiclave and Vapocide™ liquid chemical sterilant and inspected for corrosion, pitting, razing, and cracking using the scanning electron microscope and steriomicroscopic equipment.

#### **Biological Indicator Evaluation:**

The purpose of this study was to confirm that the biological indicators currently indicated for use with the Harvey Chemicalve sterilizer can be used with the Vapocide™ liquid chemical sterilant solution.

#### **Residue Testing:**

The objective this testing was to determine if formaldehyde residues remained on instruments processed in the Harvey Chemiclave Sterilizer using Vapocide™ liquid chemical sterilant solution.

#### **Packaging Evaluation for Sterilant Penetration:**

The objective of this testing was to determine the penetration ability of unsaturated chemical vapors produced from Vapocide™ through and into typical sterilization packaging during the Harvey Chemiclave process.

#### **Toxicity Testing**

Toxicity testing was performed on the Vapocide™ liquid chemical sterilant solution to determine toxicity. The following is a summary of the toxicity testing:

##### **Skin Irritation:**

This study was performed to determine if exposure to Vapocide™ produces skin irritation. This testing was performed by Gibraltar Laboratories using Vapocide™ and albino rabbits according to 40 CFR 158.135 and 158.70, Paragraph C, Pesticide Assessment Guidelines Subdivision F: Hazard Evaluation Human and Domestic Animals, Series 81-5. The results of this testing showed that the Vapocide™ liquid chemical sterilant is not a primary dermal irritant.

##### **Ocular Irritation:**

This study was performed to determine the ocular irritation potential of Vapocide™ following instillation in the eyes in rabbits. This testing was performed by Gibraltar Laboratories using Vapocide™ and albino rabbits according to 40 CFR

158.135 and 158.70, Paragraph C, Pesticide Assessment Guidelines Subdivision F: Hazard Evaluation Human and Domestic Animals, Series 81-4. The results of this testing showed that the Vapocide™ liquid chemical sterilant produced transient irritation in the eyes of six rabbits. This was resolved by 14 days after exposure to Vapocide™.

**Sensitization:**

This testing was performed to determine the sensitization potential of Vapocide™ to cause allergic contact dermatitis in guinea pigs. This testing was performed by Gibraltar Laboratories according to 40 CFR 158.135 and 158.70, Paragraph C, Pesticide Assessment Guidelines Subdivision F: Hazard Evaluation Human and Domestic Animals, Series 81-6, pages 59-62. The results of this testing showed that Vapocide™ did not produce allergenic contact dermatitis following the challenge in guinea pigs.

**Mutagenicity:**

This testing was performed to determine if Vapocide™ liquid chemical sterilant is mutagenic at the histidine locus in the *Salmonella typhimurium* strains of Ames. This testing was performed by Gibraltar Laboratories according to the Ames technique. The results of this testing showed that a 1% solution of Vapocide™ did not produce a mutagenic effect in the Ames Spot test employing five tester strains of auxotrophic *Salmonella typhimurium*.

**Acute Dermal Toxicity:**

This testing was performed to determine the acute dermal toxicity of Vapocide™ in rabbits at the dose of two grams per kilogram of body weight. This testing was performed by Gibraltar Laboratories according to 40 CFR 158.135 and 158.70, Paragraph C, Pesticide Assessment Guidelines Subdivision F: Hazard Evaluation Human and Domestic Animals, Series 81-2. The results of this testing showed that the dermal LD<sub>50</sub> of Vapocide™ in rabbits was considered to be greater than two grams per kilogram.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

JUN 16 1998

Cottrell, Ltd.  
C/O Mr. Mark Brown  
King & Spaulding  
1730 Pennsylvania Avenue, N.W.  
Washington, D.C. 20006-4706

Re: K970726  
Vapocide™  
Regulatory Class: Unclassified  
Product Code: MED  
Dated: February 23, 1998  
Received: February 23, 1998

Dear Mr. Brown:

This letter is written in response to your letter of June 5, 1998. We have reviewed your appeal of our May 18, 1998 letter and have determined that the above referenced 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.

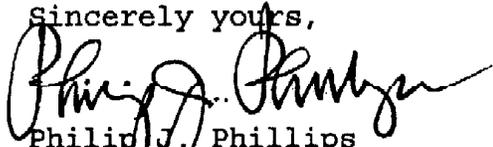
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



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

Enclosure

# ATTACHMENT E

510(k) Number (if known): K970726

Device Name: VAPOCIDE™

## Indications For Use:

Vapocide™ is a sterilant solution intended to be used only in the Harvey Chemiclave Sterilizer to sterilize medical and dental surgical instruments and equipment. Vapocide is intended to be a direct substitute for Vapo-Steril. Vapocide is recommended for use in the following Chemiclave models: Model E, 4000, 5000, 5500, 6000, 7000, 8000, and EM series sterilizers.

Vapocide is compatible with Chemiclave cycle parameters as follows:

Model E, 4000, 5000, 5500, 6000, EM 5000, EM 5500, EM 6000

- Operating pressure: 20-40 psi (1.41-2.82 kg/cm<sup>2</sup>)
- Operating Temperature: 132±2°C (270 ± 5°F)
- Maximum load: 3.3 pounds (1.5 kg) for models with 8 and 10 in. diameter chambers

Model 7000 and 8000

- Operating pressure: approximately 25 psi
- Operating Temperature: 132 + 6, -0°C
- Maximum load: 3.3 pounds (1.5 kg)

Vapocide is compatible with but not limited to the following instruments and material types:

- Surgical and cutting instruments, handpieces, and similar items
  - Plastic materials recommended are: Polysulfone, Phenolic, Epoxy, Polyphenylene, Oxide, Polyester, Polypropylene
- Note: Polycarbonate is not chemically compatible

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

Concurrence of CDRM, Office of Device Evaluation (ODE)

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

510(k) Number K970726

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

OR

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number (if known): K970726

Device Name: VAPOCIDE<sup>TM</sup>

Indications For Use:

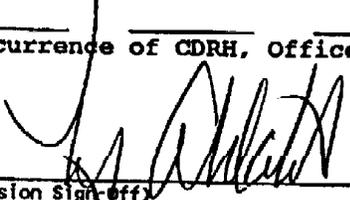
Vapocide<sup>TM</sup> is not compatible with the following materials:

- Linen, textiles or fabrics
- Liquids and agars
- Items contained in tightly woven packs or wraps
- Plastics that cannot tolerate temperature in excess of 132°C (270°F)
- Nylon tubing & bags - inhibit penetration of chemical vapors

Vapocide is not recommended for use for "flash" sterilization cycles.

(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 Dental, Infection Control,  
and General Hospital Devices

510(k) Number K970726

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

OR

Over-The-Counter Use

(Optional Format 1-2-96)