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K993042

Section C.

510(k) Summary

August 2000

1. 510(k) Summary of the Safety and Effectiveness of Rapicide™ High Level Disinfectant and Sterilant.

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   b. Name of the Device:

Trade Name:	Rapicide™ High Level Disinfectant and Sterilant.
Common name:	Liquid chemical sterilant and high-level disinfectant.
Classification name:	Not classified.

   c. Predicate name

   Wavcide-01 Solution.

d. Summary of the substantial equivalence (SE) of Rapicide™ High Level Disinfectant and Sterilant to Wavicide-01 Solution

Rapicide™ High Level Disinfectant and Sterilant and Wavicide-01 Solution are both intended for the high-level disinfection, or sterilization of clean, heat-sensitive medical devices. The active ingredient of both Rapicide™ High Level Disinfectant and Sterilant and Wavicide-01 Solution is 2.5 ± 0.1% w/v glutaraldehyde at pH values of about 6.0 to 7.0. Both Rapicide™ High Level Disinfectant and Sterilant and Wavicide-01 Solution are stabilized formulations of glutaraldehyde packaged ready-to-use without a requirement for additional buffering activation. The formulations for both Rapicide™ High Level Disinfectant and Sterilant and Wavicide-01 Solution contain non-ionic detergents, silicone antifoam chemicals, and corrosion inhibitors as inactive ingredients. Wavicide-01 Solution is a legally marketed product. For these reasons, Rapicide™ High Level Disinfectant and Sterilant is substantially equivalent (SE) to Wavicide-01 Solution.

e. Summary description of Rapicide™ High Level Disinfectant and Sterilant.

Rapicide™ High Level Disinfectant and Sterilant is a ready-to-use solution with an active ingredient of 2.5 ± 0.1% w/v glutaraldehyde, with a slightly acidic pH value of 6.3 to 6.7. The patented formulation (U.S. Pat. Reg. No. 4,748,279) includes a non-ionic detergent for improved wetting of surfaces. The glutaraldehyde concentration is stabilized by means of a buffer to pH 6.3 to 6.7. Other formula ingredients include a corrosion inhibitor, silicone antifoam chemical, and dyes. The formula is about 90% purified water. The ingredients of Rapicide™ High Level Disinfectant and Sterilant are similar to those in the predicate, Wavicide-01 Solution.

f. Summary of the intended use of Rapicide™ High Level Disinfectant and Sterilant

Rapicide™ High Level Disinfectant and Sterilant is labeled and intended for use in automatic endoscope reprocessing machines at 35°C, for use and re-use for 28 days, or until the glutaraldehyde concentration decreases to 1.5% whichever occurs first, for the high-level disinfection or sterilization of critical and semi-critical clean heat-sensitive medical devices. Rapicide™ High Level Disinfectant and Sterilant will sterilize with an exposure of seven (7.0) hours forty (40) minutes at 35°C at concentrations ≥ the minimum recommended concentration (MRC) of 1.5% glutaraldehyde. Rapicide™ High Level Disinfectant and Sterilant will high-level disinfect with an exposure of five (5.0) min. at 35°C at glutaraldehyde concentrations ≥ the MRC. As evaluated in an Environmental Protection Agency (EPA) Re-Use Test Protocol, Rapicide™ High Level Disinfectant and Sterilant is chemically stable, and lost glutaraldehyde concentration during 28 days at 35°C only as a result of inadvertent dilution by rinse water carried into the disinfectant by washed and rinsed respiratory therapy equipment. Rapicide™ High Level Disinfectant and Sterilant is intended to be used with a test kit to monitor the glutaraldehyde concentration. The test kit is 3M Comply™, SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No. 3983 MM.

g. Summary of the technological characteristics of Rapicide™ High Level Disinfectant and Sterilant compared to Wavicide-01 Solution.

The essential technological characteristic of both Rapicide™ High Level Disinfectant and Sterilant and the predicate, Wavicide-01 Solution, is that the active ingredient, nominally 2.5% glutaraldehyde, is stable, and thus the formulations are packaged as ready-to-use without requiring the addition of an alkaline buffer at the time of use. Both Rapicide™ High Level Disinfectant and Sterilant and Wavicide-01 Solution achieve the chemical stability by buffering the formulas to slightly acidic pH values. The appropriate pH range for use of Rapicide™ High Level Disinfectant and Sterilant is pH 6.0 – 7.0. A further advantage of this chemical stability is that the temperature of the formula can be heated slightly from ambient temperatures (18 to 25°C) to 35°C without losing glutaraldehyde monomers to polymers over a period of about 28 days. Rapicide™ High Level Disinfectant and Sterilant is intended and labeled for use at 35±1°C. The high-level disinfection exposure is 5.0 min at 35±1° for Rapicide™ High Level Disinfectant and Sterilant and the sterilization exposure is 7.0 hrs and 40 minutes at 35±1°C. By comparison, the label high-level disinfection exposure time for Wavicide-01 Solution at 22°C is 45.0 min, and the sterilization exposure time at 22°C is 10.0 hrs.

h. Summary discussion of non-clinical tests of Rapicide™ High Level Disinfectant and Sterilant.

h-1. Antimicrobial efficacy tests.

Rapicide™ High Level Disinfectant and Sterilant was stressed for 28 days at 35°C in an Environmental Protection Agency (EPA) Re-Use Test. The glutaraldehyde concentration decreased to about 1.9%, due to inadvertent dilution by rinse water carried into the Rapicide™ High Level Disinfectant and Sterilant by respiratory therapy equipment, and glutaraldehyde removed and rinsed away also by respiratory therapy equipment. The stressed Rapicide™ High Level Disinfectant and Sterilant was further diluted with synthetic hard water at 400 ppm $CaCO_3$ to 1.5% glutaraldehyde, pH value 6.2 ± 0.1, the minimum recommended concentration (MRC) for MediVators 5 Minute High-Level Disinfectant. This stressed and further diluted Rapicide™ High Level Disinfectant and Sterilant was considered "worst case" and all antimicrobial efficacy tests used this "worst case" Rapicide™ High Level Disinfectant and Sterilant.

h-2. Exposure time-sterilization response curve.

Groups of sixty (60) unglazed porcelain cylinders or silk suture loops (carriers) labeled with *C. sporogenes* or *B. subtilis* spores according to the methods of the AOAC Sporicidal Activity of Disinfectants Test 966.04 were exposed to worst case Rapicide™ High Level Disinfectant and Sterilant for various increasing exposure times at 35±1°C. *B. subtilis*-labeled silk loops were the most resistant of the four spore-carrier combinations. All (100%) of 60 spore-labeled carriers were sterilized by worst case Rapicide™ High Level Disinfectant and Sterilant within 4.0 hrs at 35°C. As a result of these tests, 7.0 hrs and 40.0 min at 35°C was accepted as the sterilization exposure for worst case Rapicide™ High Level Disinfectant and Sterilant at its MRC.

h-3. Full AOAC Sporicidal Activity of Disinfectants Test 966.04.

Three lots of worst case Rapicide™ High Level Disinfectant and Sterilant at its MRC passed an AOAC Sporicidal Activity of Disinfectants Test 966.04 with an exposure of 5.0 hrs at 35°C. The sterilization label claim for Rapicide™ High Level Disinfectant and Sterilant is 7 hours 40 minutes at 35°C.

h-4 Confirmative AOAC Sporicidal Activity of Disinfectants Test 966.04.

Two lots of worst case Rapicide™ High Level Disinfectant and Sterilant passed an AOAC Sporicidal Activity of Disinfectants Test 966 04, using 30 spore-labeled carriers per spore and carrier combination with an exposure of 5.0 hrs ant 35°C. The confirmative test was done at ViroMed Biosafety Laboratories and MicroBioTest Inc.

h-5. Quantitative Tuberculocidal Activity of Rapicide™ High Level Disinfectant and Sterilant.

Two lots of worst case Rapicide™ High Level Disinfectant and Sterilant at 35±1°C, one lot of Wavicide-01 Solution at 2.0% glutaraldehyde at 22±1°C, and 0.8% phenol at 25±1°C as a control of resistance of *M. bovis var. BCG* were tested in a quantitative rate of kill test against M. bovis var. *BCG*. This test was repeated on three different test dates with a different culture of *M. bovis var. BCG* on each test date. The cultures of *M. bovis var. BCG* contained 5.0% calf serum v/v. Worst case Rapicide™ High Level Disinfectant and Sterilant at 35°C killed 3.5×10^7 Colony Forming Units (CFU) of *M. bovis var BCG* within 2.0 min. The predicate Wavicide-01 Solution at 2.0% glutaraldehyde 22±1°C required 45.0 min to kill the *M. bovis var. BCG* in these same tests. The 0.8% phenol at 25°C required 20 to 30 min to kill 50% of these *M. bovis var. BCG* cultures. From these data the high-level disinfection label claim for worst case Rapicide™ High Level Disinfectant and Sterilant at its MRC of 1.5% glutaraldehyde was set at 5.0 min at 35±1°C.

h-6. AOAC Use Dilution Tests as a Function of Exposure Time and Glutaraldehyde Concentration.

Stainless steel penicylinders (cylinders) were labeled with *S. aureus or P. aeruginosa* according to the methods of the AOAC Use Dilution Tests. Sixty (60) of these bacteria-labeled cylinders were exposed to worst case Rapicide™ High Level Disinfectant and Sterilant at 1.5% glutaraldehyde at each time of 2.5, 5.0, and 10.0 min at 35±1°C. Additionally, sixty (60) of these bacteria-labeled cylinders were exposed to worst case Rapicide™ High Level Disinfectant and Sterilant at either 1.5% or 1.0% glutaraldehyde disinfected all of these cylinders within 2.5 min at 35±1°C. We conclude from these tests that the high-level disinfection claim for Rapicide™ High Level Disinfectant and Sterilant of 5.0 min at 35±1°C has a margin-of-safety both in exposure time and glutaraldehyde concentration.

h-7. AOAC Use Dilution Tests.

Stainless steel cylinders were labeled with *S. aureus, P. aeruginosa,* and *S. choleraesuis* according to the methods of the AOAC Use Dilution Tests. Sixty (60) of these bacteria-labeled cylinders each were exposed to three different lots of worse case Rapicide™ High Level Disinfectant and Sterilant at 1.5% glutaraldehyde, pH 6.1, for 5 min at 35±1°C. All (100%) cylinders were disinfected of all three test bacterial species for all three lots of worst case Rapicide™ High Level Disinfectant and Sterilant within 5 min at 35±1°C. We conclude from these results that worst case Rapicide™ High Level Disinfectant and Sterilant passes the AOAC Use Dilution Test within its high-level disinfection claim of 5 min at 35±1°C.

h-8. Summary of fungicidal activity of Rapicide™ High Level Disinfectant and Sterilant.

T. mentagrophytes, C. albicans, or *A. niger* were exposed to worst case Rapicide™ High Level Disinfectant and Sterilant and to worst case Rapicide™ High Level Disinfectant and Sterilant further diluted to 1.0% glutaraldehyde for 2.5, 5.0, 10.0 and 15.0 min at 35±1°C. according to the methods of the AOAC Fungicidal Activity of Disinfectants Test 955.17. Worst case Rapicide™ High Level Disinfectant and Sterilant at 1.5% or 1.0% glutaraldehyde killed all three of these species of fungi with 2.5 min at 35±1°C. These results indicate there is a margin-of-safety in the high-level disinfection label claim of 5.0 min at 35±1°C for worst case Rapicide™ High Level Disinfectant and Sterilant for both the exposure time, and glutaraldehyde concentration for fungicidal activity.

h-9. Summary of virucidal activity of Rapicide™ High Level Disinfectant and Sterilant.

Two lots of worst case Rapicide™ High Level Disinfectant and Sterilant at 1.5% glutaraldehyde, and further diluted to 1.0% glutaraldehyde were tested against viruses at 35±1°C for 5.0 min. Calf serum at 5% v/v was added to the virus cultures. Both glutaraldehyde concentrations, 1.5% and 1.0%, killed ≥ 99.9% of Poliovirus type 1, Adenovirus type 2, Influenza virus type A2, Herpes simplex virus type 1 and type 2, and the Human Immunodeficiency virus (HIV) type 1, as required for a virucidal claim. The tests at 1.0% glutaraldehyde (the MRC for Rapicide™ High Level Disinfectant and Sterilant is 1.5% glutaraldehyde) indicate a margin-of-safety in the high-level disinfection claim for Rapicide™ High Level Disinfectant and Sterilant of 5.0 min at 35±1°C for virucidal activity.

h-10. Summary of simulated use tests of Rapicide™ High Level Disinfectant and Sterilant in the sterilization exposure mode.

Three Olympus brand flexible endoscopes; a gastroscope, colonoscope, and sigmoidoscope; were loaded in insertion tube and umbilical tube channels with ≥ 10^6 CFU of *B. subtilis*, and allowed to dry at ambient temperature for 30 min. Without further processing these endoscopes were placed into Rapicide™ High Level Disinfectant and Sterilant that had been diluted to 1.5% glutaraldehyde with synthetic hard water. The interior channels were filled with Rapicide™ High Level Disinfectant and Sterilant using an Olympus CW3-all channel irrigator or MH-946 channel irrigator for colonoscopes, and held for 5.0 hrs at 35±1°C. After the sterilization exposure, the channels were measured for surviving *B. subtilis*. More than six $\log_{10}$ of *B. subtilis* were killed. This test was repeated several times for each endoscope. These results indicate that the sterilization claim of 7 hrs 40 minutes at 35±1°C for Rapicide™ High Level Disinfectant and Sterilant is valid under simulated use conditions.

h-11. Summary of simulated use tests of Rapicide™ High Level Disinfectant and Sterilant in the high-level disinfection mode.

The interior channels of the insertion tube and the umbilical tube of three different types of Olympus-brand flexible endoscopes; a gastroscope, colonoscope, and sigmoidoscope; were filled with ≥ 10^6 CFU of *M. bovis var. BCG* using a CW3-all channel irrigator. The endoscopes were allowed to dry for 30 min at ambient temperatures. These *M. bovis var. BCG*-labeled endoscopes were placed into a MediVators automatic endoscope reprocessing machine set for manual operation. The Rapicide™ High Level Disinfectant and Sterilant diluted with synthetic hard water to 1.5% glutaraldehyde filled the channels and flooded the endoscopes for 5.0 min at 35±1°C. Without any pre-or post-rinses, the endoscope channels were measured for surviving CFU of *M. bovis var. BCG*. Each endoscope was tested twice. There were no surviving CFU of *M. bovis var BCG* in five of six endoscopes tested, and four CFU recovered from one endoscope. Analysis of the four surviving CFU indicated an unusually high challenge of 1.3×10^8 CFU in the endoscope. These data support the claim that Rapicide™ High Level Disinfectant and Sterilant at 1.5% glutaraldehyde is capable of high-level disinfection with an exposure of 5.0 min at 35±1°C under conservative (no pre-or post-rinses) simulated use conditions, killing ≥ 10^5 CFU of *M. bovis var. BCG*.

h-12. Summary of clinical in-use tests of Rapicide™ High Level Disinfectant and Sterilant.

Rapicide™ High Level Disinfectant and Sterilant was tested in a clinical environment at a Fort Worth, TX, endoscopy clinic. Immediately after use with a patient 100 ml of sterile physiological saline solution containing 1.0% sodium bisulfite was drawn through the insertion tube and umbilical tube channels of Pentax-brand gastroscopes and colonoscopes. This sample was measured for the number of wild type aerobic bacteria within the endoscope channels, and also simulated a pre-rinse. The endoscopes were then immersed in Rapicide™ High Level Disinfectant and Sterilant at 1.5% glutaraldehyde, pH 6.1, at 35±1°C filling all interior channels for an exposure time of 5.0 min. The channels were again measured for surviving wild type bacteria. Three gastroscopes and three colonoscopes were contaminated with from 3.5×10^3 to 1.0×10^7 CFU of bacteria before exposure to Rapicide™ High Level Disinfectant and Sterilant. No (zero) bacteria were recovered after exposure to Rapicide™ High Level Disinfectant and Sterilant for 5.0 min at 35±1°C, the high-level disinfection label claim for Rapicide™ High Level Disinfectant and Sterilant.

h-13. Summary of tests to measure the reduction of glutaraldehyde following exposure of endoscopes to Rapicide™ High Level Disinfectant and Sterilant.

The interior channels and all surfaces of Olympus-brand flexible endoscopes; a gastroscope, colonoscope, and sigmoidoscope; were soaked in full-strength Rapicide™ High Level Disinfectant and Sterilant for 5.0 hrs at 35±1°C After this exposure the disinfectant was drained from the channels, and the entire endoscope was rinsed in 2.0 L of fresh tap water. The rinse was repeated a 2nd and 3rd time in 2.0 L of tap water. After these residue reduction rinses, the endoscopes were soaked in 2.0 L of distilled water for 20 hrs, and then in 2.0 L of fresh distilled water again for 4.0 hrs. The glutaraldehyde concentration in each rinse was measured by a colorimetric method able to detect 1 to 5 ppm.

After the 1st rinse, the glutaraldehyde concentration averaged 112 to 302 ppm, a 99.986% reduction. The 2nd and 3rd rinses further reduced the glutaraldehyde concentrations to 5 to 8 ppm, and 0.9 to 1.4 ppm respectively. After an extraction of 20 hrs an average of 20 to 24 ppm of glutaraldehyde was measured.

We conclude from these data that rinse directions for Rapicide™ High Level Disinfectant and Sterilant must direct for three separate rinses each in a copious volume of water or an equivalent validated rinse by an automatic endoscope reprocessing machine. These are the same directions for the rinse of the predicate, Wavicide-01 Solution as well as other legally marketed glutaraldehyde disinfectants as may be used in automatic endoscope reprocessing machines.

h-14. Summary of studies of paper strips as indicators of the glutaraldehyde concentration of Rapicide™ High Level Disinfectant and Sterilant.

A stressed lot of Rapicide™ High Level Disinfectant and Sterilant was further diluted with synthetic hard water to 1.8, 1.7, 1.6, 1.5, 1.4, and 1.3% glutaraldehyde. 3M Comply™, SteriLog™ 1.5%, Glutaraldehyde Monitor, Cat. No 3983 MM designed to fail at glutaraldehyde concentrations of ≤ 1.5% were used with the various known glutaraldehyde concentrations of Rapicide™ High Level Disinfectant and Sterilant at 35±1°C. Many Monitors (28% to 98%) also indicated discard solution at 1.6% or 1.7% glutaraldehyde at 35°C. Most Monitors (96%) indicated that glutaraldehyde was > 1.5% when the glutaraldehyde was in fact 1.8% at 35°C. We conclude that there is a legally marketed Monitor that accurately indicates to discard the Rapicide™ High Level Disinfectant and Sterilant at ≤ 1.5% glutaraldehyde, the MRC of Rapicide™ High Level Disinfectant and Sterilant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2000

Medivators, Incorporated
C/O Norman Miner, Ph.D.
Microchem Laboratory, Incorporated
7423 Airport Freeway
Fort Worth, Texas 76118

Re: K993042
Trade Name: Rapicide High Level Disinfectant and Sterilant
Regulatory Class: II
Product Code: MED
Dated: August 8, 2000
Received: August 9, 2000

Dear Dr. Miner:

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 (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 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.

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" (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,

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): K993042

Device Name: Rapicide™ High Level Disinfectant and Sterilant

Indications For Use.

Bottle label, Left panel

INDICATIONS FOR USE

Refer to the package insert for more detailed information about product usage, material compatibility, and other subjects.

STERILIZATION:

Rapicide™ High Level Disinfectant and Sterilant is intended to be used for the automated sterilization of clean, heat sensitive, critical medical equipment for which alternative methods of sterilization are not suitable. Critical medical devices are those that contact normally sterile areas of the body. Critical medical devices must be sterilized.

Rapicide™ High Level Disinfectant and Sterilant is a sterilant when used or reused, in a legally marketed Automated Endoscope Reprocessor according to Directions for Use, at a minimum recommended concentration (MRC) of 1.5% glutaraldehyde at 35°C (95°F), not to exceed 28 days, with a minimum contact or immersion time of at least 7 hours and 40 minutes.

HIGH-LEVEL DISINFECTION:

Rapicide™ High Level Disinfectant and Sterilant is intended to be used for the automated high level disinfection of clean, heat sensitive, semi-critical medical devices for which sterilization is not practical. Semi-critical medical devices may be sterilized or high-level disinfected. Semi-critical medical devices are those that contact mucous membranes or other body surfaces not normally considered sterile.

Rapicide™ High Level Disinfectant and Sterilant is a high-level disinfectant when used or reused, in a legally marketed Automated Endoscope Reprocessor according to Directions for Use, at a minimum recommended concentration (MRC) of 1.5% glutaraldehyde at 35°C (95°F), not to exceed 28 days, with a minimum contact or immersion time of at least 5 minutes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
510(k) Number K993042