

FEB - 5 2010

K091210
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Section C
510(k) Summary
ACECIDE-C High-Level Disinfectant and Sterilant

Date of Application: April 23, 2009

1. Summary of the safety and effectiveness of ACECIDE-C High-Level Disinfectant and Sterilant, a liquid chemical high-level disinfectant and sterilant.

- a. Applicant/Sponsor

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- c. Name of the Device

Trade Name: ACECIDE-C High-Level Disinfectant and Sterilant
Common Name: Liquid Chemical High-Level Disinfectant and Sterilant
Classification Name: Not Classified

- d. Predicate Name

Acecide High Level Disinfectant and Sterilant (K041984)

- e. Summary of the substantial equivalence (SE) of ACECIDE-C High-Level Disinfectant and Sterilant to the predicate Acecide High Level Disinfectant and Sterilant.

Both ACECIDE-C High-Level Disinfectant (HLD) and Sterilant and Acecide High Level Disinfectant and Sterilant are two part products which are mixed and diluted with water (ACECIDE-C only) at the time of use. Solution 1 for both ACECIDE-C

and Acecide contains concentrations of the chemicals that react to produce peracetic acid (hydrogen peroxide and acetic acid) at low pH values of about 1.0 or less. ACECIDE-C Solution 2 is a concentrated buffer solution, while Acecide Solution 2 is a dilute buffer solution. The mixed use solutions contain antimicrobial concentrations of 3100 to 3800 ppm peracetic acid. ACECIDE-C has a final pH value of about 3.4 to 3.7 and Acecide has a final pH value of about 4.0 to 4.5. Both of these products are intended for the high-level disinfection and/or sterilization of clean, heat-sensitive devices for which there is no other practical method for disinfection or sterilization. Acecide is a legally marketed sterilant. For these reasons, Acecide is an appropriate predicate device for comparisons of substantial equivalence to ACECIDE-C.

f. Summary description of ACECIDE-C High-Level Disinfectant and Sterilant.

ACECIDE-C High-Level Disinfectant and Sterilant is packaged in two separate plastic bottles: **ACECIDE-C 6.8% Peracetic Acid Concentrate Solution 1** is a concentrate of acetic acid and hydrogen peroxide, which react with each other in the presence of a catalyst and stabilizer to form 6.2 – 6.8 % w/w peracetic acid at a pH value of <1. **ACECIDE-C Buffer Concentrate Solution 2** contains a sequestrant, an anti-corrosive, and buffer salts for a pH value of about 8.7 to 9.7. At the time of use, one part of **ACECIDE-C 6.8% Peracetic Acid Concentrate Solution 1** and one part of the **ACECIDE-C Buffer Concentrate Solution 2** is mixed with 18 parts of tap water at 20°C for a final concentration of 3100 - 3400 ppm peracetic acid.

g. Summary of the intended use of ACECIDE-C High-Level Disinfectant and Sterilant.

ACECIDE-C is a high level disinfectant intended to disinfect reusable clean heat-sensitive semi-critical medical devices (such as flexible endoscopes) which contact mucous membranes when used at or above its minimum recommended concentration of 2000 ppm peracetic acid for 7.0 minutes at 20°C.

ACECIDE-C is a sterilant intended to sterilize reusable clean heat-sensitive critical and semi-critical medical devices (such as flexible endoscopes) which contact and potentially penetrate into sterile body areas, for which there is no other practical method of sterilization, when used at or above its minimum recommended concentration of 2000 ppm peracetic acid for 2.0 hours at 20°C.

ACECIDE-C High-Level Disinfectant and Sterilant must be tested for peracetic acid concentration at the time of each use with ACECIDE Test Strips as manufactured by Merck KGaA (Darmstadt Germany). ACECIDE Test Strips are used with ACECIDE-C use solution to ensure that the level of peracetic acid is above the minimum recommended concentration of 2000 ppm.

- h. Summary of the technological characteristics of ACECIDE -C High-Level Disinfectant and Sterilant as Compared with the Predicate, Acecide High-Level Disinfectant and Sterilant.
- i. ACECIDE-C High-Level Disinfectant and Sterilant and Acecide High-Level Disinfectant and Sterilant contain similar concentrations of peracetic acid as an active ingredient, and the use dilution of each are similar. The Acecide use dilution is about 3300 to 3800 ppm peracetic acid and gradually declines through five days of use and re-use at 25°C until its concentration decreases to 1900 ppm peracetic acid. The use dilution of ACECIDE-C starts at 3100 to 3400 ppm peracetic acid and gradually declines through five days of use and re-use at 20°C until its concentration decreases to 2000 ppm peracetic acid. In eight separate five day EPA Re-Use Tests at 20°C, the concentration of peracetic acid in ACECIDE-C never decreased below 2000 ppm before the conclusion of each study.

i-1. Summary of the AOAC Use Dilution Test using worst-case ACECIDE-C.

Stainless steel penicylinders were labeled with *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa* containing 5% v/v animal serum, and tested according to the methods of the AOAC Use Dilution Test 955.14, 955.15, and 964.02. When exposed to one lot of ACECIDE-C at a worst-case peracetic acid concentration of 2000 ppm, from a 5-day EPA Reuse Test, all (100%) of the bacteria-labeled cylinders were disinfected following exposures of 1.0, 3.0, and 5.0 minutes at 20°C.

i-2. Summary of the AOAC Fungicidal Test 955.17 using worst-case ACECIDE-C.

Cultures of *Trichophyton mentagrophytes*, *Aspergillus niger*, and *Candida albicans* with 5% v/v animal serum were tested against one lot of worst-case ACECIDE-C at 2000 ppm peracetic acid from a 5-day EPA Reuse Test according to the methods of the AOAC Fungicidal Test 955.17. All of these surrogate fungi were killed with exposures of 1.0, 2.5, and 5.0 minutes at 20°C.

i-3. Summary of the virucidal tests using worst-case ACECIDE-C.

Influenza A Virus, Herpes Simplex Virus type 1, and Adenovirus type 2, all containing 5% v/v animal serum, were killed within the limits of detection with exposure for 5.0 minutes at 20°C to ACECIDE-C at 2000 ppm peracetic acid from a 5-day EPA Reuse Test. Poliovirus type 1 was killed within the limits of detection with exposure for 7.0 minutes at 20°C. This Poliovirus test determined the exposure time of 7.0 minutes for high level disinfection for ACECIDE-C.

i-4. Summary of the mycobactericidal tests using worst-case ACECIDE-C.

Worst-case ACECIDE-C from a 5-day EPA Reuse Test, further diluted to 2000 ppm peracetic acid, killed 6.0 log₁₀ of *M. terrae* within about 4.0 min and about 8 log₁₀ were killed within 5.0 min of exposure time at 20°C.

i-5. Summary of the studies to determine the sterilization exposure time for ACECIDE-C.

One Lot of ACECIDE-C from a 5-day EPA Reuse Test, further diluted to 2000 ppm peracetic acid, was tested against 40 of each type of spore-labeled carrier with exposures of 15.0, 30.0, 60.0, 120.0, and 240.0 hours at 20°C according to the methods of the AOAC Sporicidal Test 966.04. All of the *B. subtilis*-labeled carriers were sterilized within 15.0 minutes and all of the *C. sporogenes*-labeled carriers were sterilized within 1.0 hour. A sterilization exposure time of 2.0 hours was selected to provide a margin of safety.

i-6. Summary of the results of a full three lot AOAC Sporicidal Test 966.04 of ACECIDE-C.

Three Lots of ACECIDE-C from a 5-day EPA Reuse Test, further diluted to 2000 ppm peracetic acid, passed the AOAC Sporicidal Test 966.04 with an exposure of 2.0 hours at 20°C.

i-7. Summary of the results of a Confirmatory Sporicidal Test with ACECIDE-C.

One Lot of ACECIDE-C from a 5-day EPA Reuse Test, further diluted to 2000 ppm peracetic acid, passed the Confirmatory AOAC Sporicidal Test 966.04 with an exposure of 2.0 hours at 20°C.

i-8. Summary of the results of simulated-use tests with flexible endoscopes inoculated with *M. terrae* and disinfected with ACECIDE-C.

The interior channels and exterior surfaces of a bronchoscope, gastroscope, and colonoscope were inoculated with a culture of *M. terrae* with 5% v/v animal serum and dried for one hour. The *M. terrae*-inoculated endoscopes were then exposed to worst-case ACECIDE-C from a 5-day EPA Reuse Test, further diluted to 2000 ppm peracetic acid for 5.0 or 7.0 minutes at 20°C. At least 6 log₁₀ of the *M. terrae* was killed by the ACECIDE-C within 7.0 minutes.

i-9. Summary of the results of simulated-use tests with flexible endoscopes inoculated with *B. subtilis* and sterilized with ACECIDE-C.

The interior channels and exterior surfaces of a bronchoscope, gastroscope, and colonoscope were inoculated with a culture of *B. subtilis* with 5% v/v animal serum and dried for one hour. The *B. subtilis*-inoculated endoscopes were then exposed to worst-case ACECIDE-C from a 5-day EPA Reuse Test, further diluted to 2000 ppm peracetic acid for 2.0 hours at 20°C. At least 6 log₁₀ of the *B. subtilis* was killed by the ACECIDE-C within 2.0 hours.

j. Summary description of in-use tests with ACECIDE-C.

Olympus gastroscopes and colonoscopes as received directly from patients at an endoscopy clinic, and cleaned, but not disinfected, according to standard cleaning procedures of the clinic, were exposed for 5.0 minutes at 20°C to worst-case ACECIDE-C from a 5-day EPA Reuse Test, further diluted to 2000 ppm peracetic acid. No (zero) bacteria were recovered from these endoscopes after the exposure to ACECIDE-C.

Olympus bronchoscopes as received directly from patients at a hospital, and processed as above, were exposed for 7.0 minutes to ACECIDE-C at 20°C as above. No (zero) bacteria were recovered from these endoscopes after the exposure to ACECIDE-C.

k. Summary of ACECIDE Test Strips

ACECIDE Test Strips are used with ACECIDE-C use solution to ensure that the level of peracetic acid is above the minimum recommended concentration of 2000 ppm.

The test strips are based on the same basic chemistry as other peracetic acid test strips and assay methods. Peracetic acid oxidizes iodide to iodine with starch forming a visible blue-gray/blue-black compound with iodine. This color change in the indicator paper is the visual basis for the tests strips and their reading.

ACECIDE-C must be tested for peracetic acid concentration at the time of each use with ACECIDE Test Strips as manufactured by Merck KGaA (Darmstadt Germany).

l. Summary of the conclusions drawn from the tests that indicate that ACECIDE-C High Level Disinfectant and Sterilant is as safe and as effective or better, than Acecide High Level Disinfectant and Sterilant.

We conclude that ACECIDE-C High-Level Disinfectant and Sterilant is as safe as Acecide High Level Disinfectant and Sterilant because the two products contain similar concentrations of peracetic acid throughout the use life, and are used at similar exposure temperatures. We conclude that ACECIDE-C is as antimicrobial or more antimicrobial than Acecide based on similar high level disinfection exposure times and temperatures, and that ACECIDE-C has a faster sterilization time at a lower temperature (2.0 hours at 20°C versus 5.0 hours at 25°C).



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FEB - 5 2010

Re: K091210
Trade/Device Name: ACECIDE -C High-Level Disinfectant and Sterilant
ACECIDE Test Strips
Regulation Number: 21 CFR 880.6885
Regulation Name: Liquid Chemical Sterilants/ High Level Disinfectants
Regulatory Class: II
Product Code: MED
Dated: January 7, 2010
Received: January 13, 2010

Dear Dr. Miner:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
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Enclosure

Indications for Use

510(k) Number (if known): K091210

Device Name: ACECIDE-C High-Level Disinfectant and Sterilant

Indications For Use:

ACECIDE-C is a high level disinfectant intended to disinfect reusable clean heat-sensitive semi-critical medical devices (such as flexible endoscopes) which contact mucous membranes when used at or above its minimum recommended concentration of 2000 ppm peracetic acid for 7.0 minutes at 20°C.

ACECIDE-C is a sterilant intended to sterilize reusable clean heat-sensitive critical and semi-critical medical devices (such as flexible endoscopes) which contact and potentially penetrate into sterile body areas, for which there is no other practical method of sterilization, when used at or above its minimum recommended concentration of 2000 ppm peracetic acid for 2.0 hours at 20°C.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart 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

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510(k) Number: K091210

Indications for Use

510(k) Number (if known): K091210

Device Name: ACECIDE Test Strips

Indications For Use:

ACECIDE Test Strips are used with ACECIDE-C High Level Disinfectant and Sterilant use solution to ensure that the level of peracetic acid is above the minimum recommended concentration of 2000 ppm.

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X
(21 CFR 801 Subpart 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

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