

MAY 11 2005

K041984

**ACECIDETM HIGH-LEVEL DISINFECTANT AND STERILANT  
AND  
ACECIDETM PERACETIC ACID TEST STRIPS**

510(k) Summary of Safety and Effectiveness

**Sponsor/Applicant:** Best Sanitizers, Inc.  
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Penn Valley, CA 95946  
USA

**Contact:** Mohammed R. Hay  
Director, Manufacturing  
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**Submission Correspondent:** Richard M. Ormsbee  
**Address:** Minntech Corporation  
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Fax: 763-509-1601

Best Sanitizers has supplied the following information to the U.S. Food and Drug Administration to support substantial equivalency of the Acecide<sup>TM</sup> High-Level Disinfectant and Sterilant to other sterilants currently in distribution in the United States.

**1. Device Description**

Acecide High-Level Disinfectant and Sterilant is a germicide that requires the combination of two parts, Solution 1 and Solution 2, within the Solution 2 bottle. The product is used full strength without dilution. It is packaged in two High Density Polyethylene bottles.

The active ingredients in Acecide High-Level Disinfectant and Sterilant are peracetic acid and hydrogen peroxide. As discussed in Block's<sup>1</sup> article, the mechanism of microbial action is believed to be oxidizing sulphydryl and sulfur bonds on proteins and enzymes, particularly in the cell walls.

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<sup>1</sup> Block, Seymour S., Disinfection, Sterilization and Preservation; Chapter 9 Peroxygen Compounds (pages 167-181), Lea & Febiger, 1991.

Acecide Peracetic Acid Test Strips are provided to verify that the minimum recommended concentration, 1900 ppm peracetic acid (PAA) of Acecide High-Level Disinfectant and Sterilant is present.

## 2. **Intended Use**

Acecide High-Level Disinfectant and Sterilant is intended to be used for automated sterilization or high-level disinfection of clean, heat sensitive, critical and semi-critical medical devices that are not compatible with other sterilization or high-level disinfection processes that can be biologically monitored.

Acecide High-Level Disinfectant and Sterilant should be used under the following contact conditions:

	Time	Temperature	Minimum Recommended Concentration of Peracetic Acid
Sterilization	5 hours	25°C	1900 ppm
High-Level Disinfection	5 minutes	25°C	1900 ppm

Acecide Peracetic Acid Test Strips are intended for verifying the minimum recommended concentration of peracetic acid in Acecide High-Level Disinfectant and Sterilant during reuse.

## 3. **Comparison to Another Device in Commercial Distribution Within the United States**

Acecide High-Level Disinfectant and Sterilant is comparable in its intended use to other liquid sterilants currently on the market in the United States. Acecide High-Level Disinfectant and Sterilant is similar in use and product claims to Minntech's Peract® 20 Liquid Sterilant/Disinfectant and Medivators Rapicide™ High Level Disinfectant and Sterilant.

## 4. **Summary**

Best Sanitizers has performed testing to demonstrate that Acecide High-Level Disinfectant and Sterilant and Acecide Peracetic Acid Test Strips are safe and effective when used according to the respective instructions for use.

## 5. Efficacy Testing

The following efficacy testing was performed on Acecide High-Level Disinfectant and Sterilant with all of the following conditions: at the minimum of its specifications, aged and stressed to the end of its reuse period and at its MRC (1900 ppm PAA). The testing showed the product to be sporicidal, tuberculocidal, virucidal, fungicidal and bactericidal.

AOAC sporicidal testing was performed on three lots of Acecide High-Level Disinfectant and Sterilant with the above noted conditions. Sporicidal simulated-use testing was also performed on endoscopes to show efficacy as a sterilant on actual devices.

Tuberculocidal testing was performed on three lots of Acecide High-Level Disinfectant and Sterilant with the above noted conditions. Tuberculocidal simulated-use testing was also performed on endoscopes to show efficacy as a high-level disinfectant on actual devices.

Acecide High-Level Disinfectant and Sterilant was determined to be virucidal when tested against Poliovirus Type 2, Human Immunodeficiency Virus Type 1 and Herpes simplex virus Type 1. Acecide High-Level Disinfectant and Sterilant was considered fungicidal when tested against *Trichophyton mentagrophytes*. Use-Dilution testing showed the efficacy of Acecide High-Level Disinfectant and Sterilant against *Staphylococcus aureus*, *Salmonella choleraesuis* and *Pseudomonas aeruginosa*.

Clinical testing of used endoscopes further supports the efficacy of Acecide High-Level Disinfectant and Sterilant when used under the directions of the Directions for Use. Testing determined residues of Acecide High-Level Disinfectant and Sterilant remaining on endoscopes after sterilization or high-level disinfection and rinsing were not significant.

## 6. Biocompatibility Testing

Standard patient toxicity testing evaluated the effect of residues. Testing included: cytotoxicity, hemolysis and acute toxicity testing.

Biocompatibility testing has demonstrated that Acecide High-Level Disinfectant and Sterilant is safe for the patient when used according to the Directions for Use.

## 7. Material Compatibility

Material compatibility testing demonstrates that Acecide High-Level Disinfectant and Sterilant can be used with endoscopes and a wide range of materials. Testing included soaking and reprocessing of common materials and endoscopes for the estimated lifetime of the items.

Material compatibility testing has demonstrated that Acecide High-Level Disinfectant and Sterilant is compatible with the materials and devices listed and used according to the Directions for Use.

**8. Stability**

Stability studies were performed according to the FDA Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants guidance document (1-3-2000). Studies demonstrated that the chemical and physical stability of Acecide High-Level Disinfectant and Sterilant were within specifications at the labeled expiration date.

**9. Test Strip**

Acecide Peracetic Acid Test Strips demonstrated the ability to consistently and accurately test the germicide at its MRC of 1900 ppm peracetic acid when used according to the Directions for Use.



MAY 11 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Best Sanitizers, Incorporated  
C/O Mr. Richard M. Ormsbee  
Senior Regulatory Affairs Specialist  
Minntech Corporation  
14605 28<sup>th</sup> Avenue North  
Minneapolis, Minnesota 55447-4822

Re: K041984  
Trade/Device Name: Acecide™ High-Level Disinfectant and Sterilant  
Regulation Number: 880.6885  
Regulation Name: Liquid Chemical Sterilants/ High Level Disinfectants  
Regulatory Class: II  
Product Code: MED  
Dated: March 29, 2005  
Received: March 30, 2005

Dear Mr. Ormsbee:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.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

## Indications for Use

510(k) Number (if known): K041984

Device Name: Acecide™ High-Level Disinfectant and Sterilant

### Indications for Use:

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Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
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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