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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   b. Application Correspondent

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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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Best Sanitizers, Incorporated
C/O Norman Miner, Ph. D.
President/Study Director
MicroChem Laboratory, Incorporated
1107 – C South Airport Circle
Euless (Dallas), Texas 76040

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,
Infection Control, and Dental Devices
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Center for Devices and
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Enclosure