

K 980683

MAY 1 1998

Date 2/20/98

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

Virginia C. Weinknecht  
Regulatory Affairs Specialist  
Becton Dickinson Microbiology Systems  
7 Loveton Circle  
Sparks, MD 21152-0999

NAME OF DEVICE:

Trade Name: Trovafloxacin, 10  $\mu$ g, Sensi-Discs  
Catalog Numbers 4331715 and 4331716

Common Name/Description: Antimicrobial Susceptibility Test Discs

Classification Name: Antimicrobial Susceptibility Test Discs

PREDICATE DEVICE:

Other BBL<sup>®</sup> Sensi-Discs<sup>®</sup> such as  
Ciprofloxacin, 5 mcg, Sensi-Disc<sup>®</sup>

DEVICE DESCRIPTION:

INTENDED USE:

Antimicrobial Susceptibility Test Discs are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Trovafloxacin Sensi-Discs<sup>®</sup> are intended for use in determining the susceptibility to Trovafloxacin of a wide range of bacteria, as described under Indications For Use below. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobial manufacturer, Roerig, a Division of Pfizer Inc., and received FDA approval under NDA Nos. 20-759 and 20-760.

INDICATIONS FOR USE:

Use of BBL<sup>®</sup> Trovafloxacin Sensi-Discs<sup>®</sup> for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Trovafloxacin. Trovafloxacin has been shown to

be active against most strains of microorganisms listed below, as described in the Roerig package insert for this antimicrobial.

**Active In Vitro and In Clinical Infections Against:**

**Aerobic Gram-Positive Microorganisms**

*Enterococcus faecalis* (many strains are only moderately susceptible)

*Staphylococcus aureus* (methicillin-susceptible strains)

*Staphylococcus epidermidis* (methicillin-susceptible strains)

*Streptococcus agalactiae*

*Streptococcus pneumoniae* (penicillin-susceptible strains)

*Streptococcus pyogenes*

Viridans group streptococci

**Aerobic Gram-Negative Microorganisms**

*Escherichia coli*

*Gardnerella vaginalis*

*Haemophilus influenzae*

*Haemophilus parainfluenzae*

*Klebsiella pneumoniae*

*Moraxella catarrhalis*

*Neisseria gonorrhoeae*

*Proteus mirabilis*

*Pseudomonas aeruginosa*

**Anaerobic Microorganisms**

*Bacteroides fragilis*

*Peptostreptococcus* species

*Prevotella* species

**Other Microorganisms:**

*Chlamydia pneumoniae*

*Chlamydia trachomatis*

*Legionella pneumophila*

*Mycoplasma pneumoniae*

**Active In Vitro Only Against:**

**Aerobic Gram-Positive Microorganisms**

*Streptococcus pneumoniae* (penicillin-resistant strains)

**Aerobic Gram-Negative Microorganisms**

*Citrobacter freundii*

*Enterobacter aerogenes*

*Morganella morganii*

*Proteus vulgaris*

**Anaerobic Microorganisms**

*Bacteroides distasonis*

*Bacteroides ovatus*

*Clostridium perfringens*

**Active In Vitro Only Against (continued):**

**Other Microorganisms:**

*Mycoplasma hominis*

*Ureaplasma urealyticum*

**PRODUCT DESCRIPTION:**

Trovafloxacin Susceptibility Test Discs are prepared by impregnating high quality paper with accurately determined amounts of Trovafloxacin supplied by the manufacturer, Roerig. Each Trovafloxacin disc is clearly marked on both sides with the agent and content. Trovafloxacin discs are furnished in cartridges of 50 discs each. Trovafloxacin cartridges are packed as either a single cartridge in a single box, or in a package containing ten cartridges.

Agar diffusion methods employing dried filter paper discs impregnated with specific concentrations of antimicrobial agents were developed in the 1940's. In order to eliminate or minimize variability in the testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the National Committee for Clinical Laboratory Standards (NCCLS) and is periodically updated. The latest NCCLS documents are M2-A6 (1/97) and M100-S7 (1/97).

Discs containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates [or Haemophilus Test Medium Agar for *Haemophilus influenzae* or Mueller Hinton Agar with 5% Sheep Blood for *Streptococcus pneumoniae*] inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the discs are measured and compared with established zone size ranges for individual antimicrobial agents in order to determine the agent(s) most suitable for use in antimicrobial therapy. The determination as to whether the organism in question is susceptible (S), intermediate (I), or resistant (R) to an antimicrobial agent is made by comparing zone sizes to those found in the respective organism tables of National Committee for Clinical Laboratory Standards (NCCLS) Document M2-A6 ("Performance Standards for Antimicrobial Disk Susceptibility tests - Sixth Edition, Approved Standard", 1/97) and of NCCLS Document M100-S8

("Performance Standards for Antimicrobial Susceptibility Testing", Eighth Informational Supplement, 1/98).

PERFORMANCE DATA:

See attached Roerig product insert section on Susceptibility Tests - Diffusion Techniques for TROVAN™ Tablets (trovafloxacin mesylate tablets) and TROVAN™ I.V. (alatrofloxacin mesylate injection) for intravenous infusion.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

MAY 1 1998

Virginia C. Weinknecht  
Regulatory Affairs Specialist  
Becton Dickinson Microbiology Systems  
7 Loveton Circle  
Sparks, Maryland 21152-0999

Re: K980683  
Trade Name: Trovafloxacin 10µg, Sensi-Disc®  
Regulatory Class: II  
Product Code: JTN  
Dated: February 20, 1998  
Received: February 23, 1998

Dear Ms. Weinknecht:

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 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 requirement, 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.

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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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) 594-4588. 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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: Trovafoxacin, 10 µg, Sensi-Disc®

Indications For Use:

Use of BBL Trovafoxacin Sensi-Discs® for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Trovafoxacin. Trovafoxacin has been shown to be active against most strains of microorganisms listed below, as described in the Roerig package insert for this antimicrobial.

**Active In Vitro and In Clinical Infections Against:**

**Aerobic Gram-Positive Microorganisms**

<i>Enterococcus faecalis</i> (many only mod. suscept.)	<i>Streptococcus agalactiae</i>
<i>Staphylococcus aureus</i> (meth. suscept.)	<i>Streptococcus pneumoniae</i> (pen. suscept.)
<i>Staphylococcus epidermidis</i> (meth. suscept.)	<i>Streptococcus pyogenes</i>
Viridans group streptococci	

**Aerobic Gram-Negative Microorganisms**

<i>Escherichia coli</i>	<i>Moraxella catarrhalis</i>
<i>Gardnerella vaginalis</i>	<i>Neisseria gonorrhoeae</i>
<i>Haemophilus influenzae</i>	<i>Proteus mirabilis</i>
<i>Haemophilus parainfluenzae</i>	<i>Pseudomonas aeruginosa</i>
<i>Klebsiella pneumoniae</i>	

**Anaerobic Microorganisms**

<i>Bacteroides fragilis</i>	<i>Prevotella</i> species
<i>Peptostreptococcus</i> species	

**Other Microorganisms**

<i>Chlamydia pneumoniae</i>	<i>Legionella pneumophila</i>
<i>Chlamydia trachomatis</i>	<i>Mycoplasma pneumoniae</i>

**Active In Vitro Only Against:**

**Aerobic Gram-Positive Microorganisms**

*Streptococcus pneumoniae* (penicillin-resistant strains)

**Aerobic Gram-Negative Microorganism**

<i>Citrobacter freundii</i>	<i>Morganella morganii</i>
<i>Enterobacter aerogenes</i>	<i>Proteus vulgaris</i>

**Anaerobic Microorganisms**

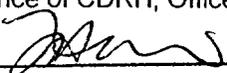
<i>Bacteroides distasonis</i>	<i>Clostridium perfringens</i>
<i>Bacteroides ovatus</i>	

**Other Microorganisms**

<i>Mycoplasma hominis</i>	<i>Ureaplasma urealyticum</i>
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number     K980683    

Prescription Use  
Per 21 CFR 801.109

OR

Over-The-Counter Use \_\_\_  
Optional Format 1-2-96