DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 28 1997

Virginia C. Weinknecht
Regulatory Affairs Specialist
Becton Dickinson Microbiology Systems
P.O. Box 243
Cockeysville, Maryland 21030-0243

Re: K972098
Trade Name: Fosfomycin, 200 mg, Sensi-Disc®
Regulatory Class: II
Product Code: JTN
Dated: June 2, 1997
Received: June 4, 1997

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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,

Steven Gutman

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

K 973098

Date 6/2/97

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

Virginia C. Weinknecht
Regulatory Affairs Specialist
Becton Dickinson Microbiology Systems
P.O. Box 243
Cockeysville, MD 21030-0243

NAME OF DEVICE:

Trade Name:	Fosfomycin, 200 mcg, Sensi-Discs Catalog Numbers 4331709, 4331710
Common Name/Description:	Antimicrobial Susceptibility Test Discs
Classification Name:	Antimicrobial Susceptibility Test Discs

PREDICATE DEVICE: Other BBL® Sensi-Discs® such as Ciprofloxacin, 5 mcg, Sensi-Disc®

DEVICE DESCRIPTION:

INTENDED USE:

Antimicrobial Susceptibility Test Discs are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Fosfomycin Sensi-Discs® are intended for use in determining the susceptibility to Fosfomycin of a wide range of bacteria, including *Enterococcus faecalis, Enterococcus faeclum, Escherichia coli, Citrobacter diversus, Citerobacter freundii, Enterobacter aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris,* and *Serratia marcesceus.* Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer, Forest Pharmaceuticals, Inc., and received FDA approval under NDA No. 50-717.

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Device Name: Fosfomycin, 200 mg, Sensi-Disc®

Indications For Use:

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

Active *In Vitro* and In Clinical Infections Against:

Aerobic Gram-Positive Microorganisms

Enterococcus faecalis

Aerobic Gram-Negative Microorganisms

Escherichia coli

Active *In Vitro* Only Against:

Aerobic Gram-Positive Microorganisms

Enterococcus faeclum

Aerobic Gram-Negative Microorganisms

Citrobacter diversus
Citerobacter freundii
Enterobacter aerogenes
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis
Proteus vulgaris
Serratia marcesceus

(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 Clinical Laboratory Devices
510(k) Number K972098

Prescription Use ✓ OR Over-The-Counter Use ___
Per 21 CFR 801.109 Optional Format 1-2-96