K981517

JUN -9 1998

Date April 27, 1998

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:	Cefdinir, 5 μg, Sensi-Discs Catalog Numbers 4331713 and 4331714
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. Cefdinir Sensi-Discs® are intended for use in determining the susceptibility to Cefdinir 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 antimicrobic manufacturer, Parke-Davis, a Division of Warner-Lambert Co., and received FDA approval under NDA Nos. 50-739 and 50-749.

INDICATIONS FOR USE:

Use of BBL® Cefdinir Sensi-Discs® for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Cefdinir. Cefdinir has been shown to be active against most

strains of microorganisms listed below, as described in the Parke-Davis package insert for this antimicrobic.

Active *In Vitro* and In Clinical Infections Against:

Aerobic Gram-Positive Microorganisms

Staphylococcus aureus (including β-lactamase producing strains, but excluding methicillin-resistant staphylococci)
Streptococcus pneumoniae (penicillin-susceptible strains only)
Streptococcus pyogenes

Aerobic Gram-Negative Microorganisms

Haemophilus influenzae (including β-lactamase producing strains)
Haemophilus parainfluenzae (including β-lactamase producing strains)
Moraxella catarrhalis (including β-lactamase producing strains)

Active In Vitro Only Against:

Aerobic Gram-Positive Microorganisms

Staphylococcus epidermidis (methicillin-susceptible strains only)
Streptococcus agalactiae
Viridans group streptococci

Aerobic Gram Negative Microorganisms

Citrobacter diversus
Escherichia coli
Klebsiella pneumoniae
Proteus mirabilis

PRODUCT DESCRIPTION:

Cefdinir Susceptibility Test Discs are prepared by impregnating high quality paper with accurately determined amounts of Cefdinir supplied by the manufacturer, Parke-Davis. Each Cefdinir disc is clearly marked on both sides with the agent and content. Cefdinir discs are furnished in cartridges of 50 discs each. Cefdinir 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-S8 (1/98).

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 Parke-Davis product insert section on Susceptibility Tests - Diffusion Techniques for Omnicef® capsules and Omnicef® for Oral Suspension.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 9 1998

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

Re: K981517
Trade Name: Cefdinir, 5µg, Sensi-Disc
Regulatory Class: II
Product Code: JTN
Dated: April 27, 1998
Received: April 28, 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 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). 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 requirements, 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.

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

Page 1 of 1
510(k) Number (if known): _____

Device Name: Cefdinir, 5 μg, Sensi-Disc®

Indications For Use:

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Haemophilus parainfluenzae (including β-lactamase producing strains)
Moraxella catarrhalis (including β-lactamase producing stains)
Escherichia coli
Kiebsiella pneumoniae
Proteus mirabilis

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Woodly Devlois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981517

Prescription Use X
Per 21 CFR 801.109

OR

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