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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	Cefepime Sensi-Discs Catalog Numbers 31695, 31696
Common Name/Description:	Antimicrobial Susceptibility Test Discs
Classification Name:	Antimicrobial Susceptibility Test Discs
PREDICATE DEVICE:	Other BBL® Sensi-Discs® such as Cefmetazole 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. Cefepime Sensi-Discs® are intended for use in determining the susceptibility of a wide range of gram-positive and gram-negative bacteria, including *Enterobacter* spp, *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Staphylococcus aureus* (methicillin-susceptible strains only), *Streptococcus pneumoniae,* and *Streptococcus pyogenes* (Lancefield's Group A streptococci), to Cefepime. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer, Bristol-Myers Squibb, and received FDA approval under NDA No. 50-679.

INDICATIONS FOR USE:

Use of BBL® Cefepime Sensi-Discs® for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to cefepime.

PRODUCT DESCRIPTION:

Cefepime Susceptibility Test Discs are prepared by impregnating high quality paper with accurately determined amounts of Cefepime supplied by the manufacturer, Bristol-Myers Squibb Company, Princeton, New Jersey. Each Cefepime disc is clearly marked on both sides with the agent and content (FEP-30). Cefepime discs are furnished in cartridges of 50 discs each. Cefepime 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 1940s. 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-A5 (12/93) and M100-S6 (12/95).

Discs containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates [or Haemophilus Test Medium Agar for *H. influenzae*, GC II Agar with IsoVitaleX® Enrichment for *N. gonorrhoeae* or Mueller Hinton Agar with 5% Sheep Blood for *S. 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

Standards (NCCLS) Document M2-A5 ("Performance Standards for Antimicrobial Disk Susceptibility tests - Fifth Edition, Approved Standard", 12/93) and of NCCLS Document M100-S6 ("Performance Standards for Antimicrobial Susceptibility Testing", Sixth Informational Supplement, 12/95).

PERFORMANCE DATA:

See attached Bristol-Myers Squibb Company product insert for MAXIPIME®, (Cefepime Hydrochloride) for Injection.