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SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name: Levofloxacin, 5 mcg, Sensi-Discs  
Catalog Numbers 4331705, 4331706

Common Name/Description: Antimicrobial Susceptibility Test Discs

Classification Name: Antimicrobial Susceptibility Test Discs

PREDICATE DEVICE: Other BBL® Sensi-Discs® such as  
Ofloxacin, 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. Levofloxacin Sensi-Discs® are intended for use in determining the susceptibility of gram-positive and gram-negative bacteria, including *Enterococcus faecalis*, *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Enterobacter cloacae*, *Escherichia coli*, *Haemophilus influenzae*, *Haemophilus parainfluenzae*, *Klebsiella pneumoniae*, *Moraxella catarrhalis*, *Proteus mirabilis*, and *Pseudomonas aeruginosa* species to Levofloxacin. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobial manufacturer, Ortho Pharmaceutical Corporation/McNeil Pharmaceutical, and received FDA approval under NDA No. 20-634.

## INDICATIONS FOR USE:

Use of BBL® Levofloxacin Sensi-Discs® for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Levofloxacin. Levofloxacin has been shown to be active against most strains of microorganisms listed below, both *in vitro* and in clinical infections, as described in the Ortho Pharmaceutical Corporation/McNeil Pharmaceutical package insert for this antimicrobial.

### **Aerobic Gram-Positive Microorganisms**

*Enterococcus faecalis*  
*Staphylococcus aureus*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes*

### **Aerobic Gram-Negative Microorganisms**

*Enterobacter cloacae*  
*Escherichia coli*  
*Haemophilus influenzae*  
*Haemophilus parainfluenzae*  
*Klebsiella pneumoniae*  
*Moraxella catarrhalis*  
*Proteus mirabilis*  
*Pseudomonas aeruginosa*

## PRODUCT DESCRIPTION:

Levofloxacin Susceptibility Test Discs are prepared by impregnating high quality paper with accurately determined amounts of Levofloxacin supplied by the manufacturers, Ortho Pharmaceutical Corporation, Raritan, New Jersey, or McNeil Pharmaceutical, Raritan, New Jersey. Each Levofloxacin disc is clearly marked on both sides with the agent and content. Levofloxacin discs are furnished in cartridges of 50 discs each. Levofloxacin 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-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* 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 respective organism tables of National Committee for Clinical Laboratory 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 Ortho Pharmaceutical Corporation/McNeil Pharmaceutical product insert section on Susceptibility Testing Diffusion Techniques for Levaquin™ (Levofloxacin).