

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

K050062

B. Purpose for Submission:

Premarket notification to add gemifloxacin to the BBL Sensi-Disc product line

C. Measurand:

Gemifloxacin 5µg/mL

D. Type of Test:

Semi-quantitative Antimicrobial Susceptibility Test Disc

E. Applicant:

Becton Dickinson and Company

F. Proprietary and Established Names:

Gemifloxacin 5µg, BBL Sensi-Disc Antimicrobial Susceptibility Test Disks

G. Regulatory Information:

1. Regulation section:

866.1620 Antimicrobial Susceptibility Test Disc

2. Classification:

II

3. Product code:

JTN- Susceptibility Test Disc, Antimicrobial

4. Panel:

83 Microbiology

H. Intended Use:

1. Intended use(s):

These discs are used for semi-quantitative *in vitro* susceptibility testing by the agar disc diffusion test procedure of common, rapidly growing and certain fastidious bacterial pathogens. These include the *Enterobacteriaceae*, *Staphylococcus spp.*, *Pseudomonas spp.*, *Acinetobacter spp.*, *Enterococcus spp.*, *Vibrio cholerae* and, by modified procedures, *Haemophilus influenzae*, *Neisseria gonorrhoeae*, *Streptococcus pneumoniae* and other streptococci.

2. Indication(s) for use:

Use of Gemifloxacin 5µg, BBL Sensi-Disc for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to gemifloxacin. 5µg has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA approved drug insert for this antimicrobial.

Active *In Vitro* and in clinical infections against:

Streptococcus pneumoniae (including multi-drug resistant strains)

Haemophilus influenzae

Haemophilus parainfluenzae

Klebsiella pneumoniae (many strains are only moderately susceptible)

Active *In Vitro* against:

Staphylococcus aureus (methicillin-susceptible strains only)

Streptococcus pyogenes

Acinetobacter lwoffii

Klebsiella oxytoca

Proteus vulgaris

3. Special conditions for use statement(s):

Gemifloxacin exhibits *in vitro* minimal inhibitory concentrations of 0.25 µg/mL or less against most (> 90%) strains of the following microorganisms; however, the safety and effectiveness of gemifloxacin in treating clinical infections due to these microorganisms has not been established in adequate and well controlled clinical trials: *Staphylococcus aureus* (methicillin-susceptible strains only), *Streptococcus pyogenes*, *Acinetobacter lwoffii*, *Klebsiella oxytoca*, *Proteus vulgaris*.

For *Streptococcus pneumoniae*, use Mueller-Hinton Agar with 5% Sheep Blood.
For *Haemophilus influenzae* use Haemophilus Test Medium Agar.

For Prescription Use only.

4. Special instrument requirements:

None

I. Device Description:

Gemifloxacin 5µg BBL Sensi-Disc is prepared by impregnating high quality paper with accurately determined amounts of gemifloxacin supplied by the drug manufacturer. Each gemifloxacin disk is clearly marked on both sides with the agent (GEM) and drug content (5 µg). Gemifloxacin cartridges each contain 50 impregnated disks that are packed as either a single cartridge in a single box, or in a package containing ten cartridges. Gemifloxacin disks are used for semi-quantitative *in vitro* susceptibility evaluations by the agar diffusion test method.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Ciprofloxacin 5µg, BBL Sensi-Disc

2. Predicate 510(k) number(s):

K874425

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	an <i>in vitro</i> diagnostic product for clinical susceptibility testing of gram positive organisms.	same
Inoculum	Pure cultures of bacterial isolates	same
Inoculation method	Direct equated to a 0.5 McFarland	same

Differences		
Item	Device	Predicate
Antibiotic	Gemifloxacin	Ciprofloxacin

K. Standard/Guidance Document Referenced (if applicable):

The Center for Drug Evaluation and Review (CDER) pharmaceutical approved package insert, developed during clinical trial studies, was used for Interpretive Criteria and QC expected Ranges.

L. Test Principle:

Disks 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 species) inoculated with pure cultures of clinical isolates (Bauer-Kirby method). Following incubation, the plates are examined and the zones of inhibition surrounding the disks 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 categorical interpretation [susceptible (S), intermediate (I), or resistant (R)] for the organism being tested with the antimicrobial agent is made by comparing zone diameters to those found in the respective organism tables of NCCLS Document M2 (“Performance Standards for Antimicrobial Disk Susceptibility Tests) and of NCCLS Document M100 (“Performance Standards for Antimicrobial Susceptibility Testing”).

M. Performance Characteristics (if/when applicable):

(Descriptive characteristics were sufficient for this disc, because the drug studies, evaluated by CDER, generated the Interpretive Criteria and QC expected Ranges used for review of this device.)

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable (N/A)

b. *Linearity/assay reportable range:*

N/A

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

N/A

d. *Detection limit:*

N/A

e. *Analytical specificity:*

N/A

f. *Assay cut-off:*

N/A

2. Comparison studies:

a. *Method comparison with predicate device:*

N/A

b. *Matrix comparison:*

N/A

3. Clinical studies:

a. *Clinical Sensitivity:*

N/A

b. *Clinical specificity:*

N/A

c. *Other clinical supportive data (when a. and b. are not applicable):*

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

Enterobacteriaceae ≥ 20 (S), 16-19 (I), ≤ 15 (R)

Streptococcus pneumoniae ≥ 23 (S), 20-22 (I), ≤ 19 (R)

Haemophilus spp. ≥ 18 (S)

The Interpretative criteria in the manufacturer's instructions for use are the same as recommended by the FDA/CDER in the approved pharmaceutical package insert. The manufacturer's QC isolates and ranges also match the approved pharmaceutical package insert but also include QC ranges for *P. aeruginosa* or *S. aureus* that are absent from the pharmaceutical package insert but match what is recommended by NCCLS. All values will be included in the device package insert.

For some organism/antimicrobial combinations, the absence of data on resistant strains precludes defining any results other than “Susceptible”. Strains yielding MIC results suggestive of a “non-susceptible” category should be submitted to a reference laboratory for further testing.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

1. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.