

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

**A. 510(k) Number:**

K152516

**B. Purpose for Submission:**

Addition of Ceftazidime avibactam Antimicrobial Susceptibility Test Disc

**C. Measurand:**

Ceftazidime avibactam (30/20µg)

**D. Type of Test:**

Antimicrobial Susceptibility Test Disks

**E. Applicant:**

Becton, Dickinson and Company

**F. Proprietary and Established Names:**

BD BBL Sensi-Disc Ceftazidime avibactam (30/20µg). Antimicrobial Susceptibility Test Disks.

**G. Regulatory Information:**

1. Regulation section:

21 CFR 866.1620 Antimicrobial Susceptibility Test Disc

2. Classification:

Class II

3. Product code(s):

JTN – Susceptibility Test Disc, Antimicrobial

4. Panel:

83 - Microbiology

## H. Intended Use:

### 1. Intended use(s):

Antimicrobial Susceptibility Test Discs are used for semi-quantitative in vitro susceptibility testing by standardized agar diffusion test procedures. BD BBL Sensi-Disc Ceftazidime avibactam (30/20µg) is intended for use in determining the susceptibility to Ceftazidime avibactam of a wide range of bacteria, as described in the "Indications for Use" section. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobics manufacturer and received FDA approval under NDA Number 206494.

### Indication(s) for use:

Use of BD BBL Sensi-Disc Ceftazidime avibactam (30/20µg) for in vitro agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Ceftazidime avibactam. The concentration of 30/20µg 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 antimicrobics.

#### **Active In Vitro and in Clinical Infections Against:**

Complicated Intra-abdominal Infections (cIAI)

Gram-negative Microorganisms

*Escherichia coli*

*Enterobacter cloacae*

*Klebsiella pneumoniae*

*Klebsiella oxytoca*

*Proteus mirabilis*

*Providencia stuartii*

*Pseudomonas aeruginosa*

#### **Complicated Urinary Tract Infections (cUTI), including Pyelonephritis**

Gram-negative Microorganisms

*Citrobacter freundii*

*Citrobacter koseri*

*Escherichia coli*

*Pseudomonas aeruginosa*

*Enterobacter aerogenes*

*Enterobacter cloacae*

*Proteus spp.*

*Klebsiella pneumoniae*

#### **Active In Vitro Against:**

Gram-negative Microorganisms

*Morganella morganii*

*Providencia rettgeri*

*Serratia marcescens*

3. Special conditions for use statement(s):

Prescription use only

4. Special instrument requirements:

Not Applicable

**I. Device Description:**

BD BBL Sensi-Disc Ceftazidime avibactam (30/20µg) is prepared by impregnating high quality paper with accurately determined amounts of Ceftazidime avibactam(30/20µg) supplied by the drug manufacturer. Each Ceftazidime avibactam (30/20µg) disc is clearly marked on both sides with the agent and drug content. Ceftazidime avibactam (30/20µg) cartridges each contain 50 impregnated discs that are packed as a single cartridge in a single box. Ceftazidime avibactam (30/20µg) discs are used for in vitro susceptibility evaluations by the agar diffusion test method.

Agar diffusion susceptibility methods employing dried filter paper disks 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. Standardized procedures were followed for testing Ceftazidime avibactam. Those are based on standard methods published by the Clinical and Laboratory Standard Institute (CLSI) and are referenced in the FDA pharmaceutical drug package insert.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

BD BBL Sensi-Disc Ciprofloxacin 5µg, Antimicrobial Susceptibility Test Discs

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

K874425

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test Method	Antimicrobial Susceptibility testing using paper discs impregnated with an antimicrobial agent	Same
Intended Use	Antimicrobial Susceptibility Test Disks are used for <i>in vitro</i> susceptibility testing by standardized agar diffusion test procedures.	Same
Methodology	Require the user to determine categorical interpretations (S/I/R) using the measured zone diameters against CLSI/NCCLS Approved Standard, M2 and M100	Same
Inoculum	Prepared from pure isolated colonies using the direct inoculation method or growth method	Same
Inoculum Method	Directly equated to a 0.5 McFarland turbidity standard.	Same

Differences		
Item	Device	Predicate
Product Name	BD BBL Sensi-Disc Ceftazidime avibactam (30/20 µg)	BD BBL Sensi-Disc Ciprofloxacin (5µg)
Antibiotic	Ceftazidime-avibactam	Ciprofloxacin
Concentration	30µg Ceftazidime/20µg avibactam	5µg

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

CLSI M02-A12. Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard

CLSI M100-S25. Performance Standards for Antimicrobial Susceptibility Testing; Approved Standard.

**L. Test Principle:**

Discs containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates inoculated with pure cultures of clinical isolates. 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 the FDA drug insert and/or CLSI/NCCLS Document M2 (“Performance Standards for Antimicrobial Disk Susceptibility Tests”) and of CLSI/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 that CDER evaluated generated the Interpretive Criteria and Quality Control (QC) Expected Ranges used for review of this device.

1. Analytical performance:

*a. Precision/Reproducibility:*

Not applicable

*b. Linearity/assay reportable range:*

Not applicable

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

Not applicable

*d. Detection limit:*

Not applicable

*e. Analytical specificity:*

Not applicable

*f. Assay cut-off:*

Not applicable

2. Comparison studies:

*a. Method comparison with predicate device:*

Not Applicable

*b. Matrix comparison:*

Not Applicable

3. Clinical studies:

a. *Clinical Sensitivity:*

Not Applicable

b. *Clinical specificity:*

Not Applicable

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The Interpretative criteria, QC isolates and expected ranges are the same as recommended by the FDA/CDER in the approved pharmaceutical drug package insert. All values are included in the device package insert.

**Table 1. FDA Interpretive Criteria for Ceftazidime/Avibactam**

Organism	Susceptibility Interpretive Criteria (Ceftazidime/Avibactam)	
	Disk Diffusion Zone Diameter (mm)	
	S	R
<i>Enterobacteriaceae</i>	≥21	≤20
<i>Pseudomonas aeruginosa</i>	≥18	≤17

Currently, there are no intermediate interpretative criteria for Ceftazidime/Avibactam.

**N. Proposed Labeling:**

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

**O. Conclusion:**

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