

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

K112586

B. Purpose for Submission:

To obtain a substantial equivalent determination for the Ceftaroline 30µg, BBL Sensi-Disc™ Antimicrobial Susceptibility Test Disks.

C. Measurand:

Ceftaroline 30µg

D. Type of Test:

Semi-quantitative Antimicrobial Susceptibility Test Disc

E. Applicant:

Becton Dickinson and Company

F. Proprietary and Established Names:

Ceftaroline 30µg BBL™ Sensi -Disc™ Antimicrobial Susceptibility Test Disks

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JTN	II	866.1620	83 Microbiology

H. Intended Use:

1. Intended use(s):

Antimicrobial Susceptibility Test Disks are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Ceftaroline 30µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Ceftaroline of a wide range of bacterial pathogens.

2. Indications for use:

Use of Ceftaroline 30µg BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Ceftaroline. The concentration of 30µg 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 agent

Active <i>In Vitro</i> and in Clinical Infections Against:	
Gram-positive Microorganisms <i>Staphylococcus aureus</i> (including methicillin-susceptible and -resistant isolates) <i>Streptococcus pyogenes</i> <i>Streptococcus agalactiae</i> <i>Streptococcus pneumoniae</i>	Gram-negative Microorganisms <i>Escherichia coli</i> <i>Klebsiella pneumoniae</i> <i>Klebsiella oxytoca</i> <i>Haemophilus influenzae</i>
Active <i>In Vitro</i> Against:	
Gram-positive Microorganisms <i>Streptococcus dysgalactiae</i>	Gram-negative Microorganisms <i>Citrobacter koseri</i> <i>Citrobacter freundii</i> <i>Enterobacter cloacae</i> <i>Enterobacter aerogenes</i> <i>Moraxella catarrhalis</i> <i>Morganella morganii</i> <i>Proteus mirabilis</i> <i>Haemophilus parainfluenzae</i>

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

None

I. Device Description:

Ceftaroline 30µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Ceftaroline supplied by the drug manufacturer. Each Ceftaroline disk is clearly marked on both sides with the agent and drug content. Ceftaroline 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. Ceftaroline disks are used for semi-quantitative *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. Mueller Hinton Agar was selected as the test medium and a standardized procedure was developed.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Ciprofloxacin 5µg, BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk.

2. Predicate 510(k) number:

K874425

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	An <i>in vitro</i> diagnostic product for clinical susceptibility testing of aerobic gram positive and gram negative bacteria	same
Inoculum	Prepared from pure isolated colonies using the direct inoculation method or growth method	same
Inoculation method	Directly equated to a 0.5 McFarland turbidity standard	same

Difference		
Item	Device	Predicate
Antibiotic	Ceftaroline	Ciprofloxacin
Concentration	30µg	5µg

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

CLSI M02-A10 January 2009 "Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard. "CLSI M100, "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard". The Center for Drug Evaluation and Review (CDER) pharmaceutical

approved package insert, developed during clinical trial studies, was used for Interpretive Criteria and Quality Control (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 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 are sufficient for susceptibility test discs, because the drug manufacturer performed several clinical outcome studies enrolling 1300 patients, which were evaluated by FDA Center for Drug Evaluation and Research in order to grant approval of the drug Ceftaroline. These studies generated the Interpretive Criteria and Quality Control Expected Ranges which the antimicrobial susceptibility tests disk manufactures use for interpretation of results also. No additional *in vitro* diagnostic clinical studies are therefore required.

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

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

BBL™ Sensi-Disc™ Ceftaroline

<i>Zone Diameter Interpretive Chart</i>						<i>Quality Control Organisms</i>		
Antimicrobial Agent	Disc Code	Disc Potency	R	I	S	<i>E.coli</i> ATCC™ 25922	<i>S. aureus</i> ATCC 25923	<i>P.aeruginosa</i> ATCC 27853
Ceftaroline <i>Staphylococcus aureus</i> (including methicillin-resistant isolates – skin isolates only)	CPT-30	30 µg	–	–	≥ 24	26-34	26-35	–
<i>Streptococcus agalactiae</i> (skin isolates only)			–	–	≥ 26			
<i>Streptococcus pyogenes</i> (skin isolates only)			–	–	≥ 24			
<i>Streptococcus pneumoniae</i> (CABP isolates only)			–	–	≥ 27			<i>S. pneumoniae</i> ATCC 49619 31-41
<i>Haemophilus influenzae</i> (CABP isolates only)			–	–	≥ 33			<i>H. influenzae</i> ATCC 49247 29-39
<i>Enterobacteriaceae</i> (CABP and skin isolates)			≤ 19	20-22	≥ 23			

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:

Staphylococcus aureus $\geq 24\text{mm}$ (S)*

Streptococcus agalactiae $\geq 26\text{mm}$ (S)*

Streptococcus pyogenes $\geq 24\text{mm}$ (S)*

Streptococcus pneumoniae $\geq 27\text{mm}$ (S)*

Haemophilus influenzae $\geq 33\text{mm}$ (S)*

Enterobacteriaceae $\geq 23\text{ mm}$ (S) $20\text{-}22\text{ mm}$ (I) $\leq 19\text{ mm}$ (R)

S = susceptible, I = intermediate, R = resistant

* The current absence of resistant isolates precludes defining any results other than “Susceptible”. Isolates yielding MIC or disk diffusion results suggestive of “Nonsusceptible” should be subjected to additional testing.

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.