

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

A. 510(k) Number:

K082272

B. Purpose for Submission:

To obtain a substantial equivalent determination for the Voriconazole 1µg, BBL™ Sensi-Disc™.

C. Measurand:

Susceptibility to Voriconazole 1 µg

D. Type of Test:

Semi-quantitative Antimicrobial Susceptibility Test Disc

E. Applicant:

Becton, Dickinson and Company

F. Proprietary and Established Names:

Becton, Dickinson and Company, BBL™ Sensi-Disc™ Voriconazole 1µg

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):

BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks Voriconazole 1 µg are used for semi-quantitative *in vitro* susceptibility testing by the agar disc diffusion test procedure of fungal pathogens.

2. Indication(s) for use:

Use of Voriconazole 1 µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of pathogens to Voriconazole. The concentration of 1 µg has been shown to be active *in vitro* against most strains for *Candida* species listed below, as described in the FDA approved drug insert for this agent.

Active *In Vitro* and in Clinical Infections Against: *Candida albicans*, *Candida glabrata*, *Candida krusei*, *Candida parapsilosis*, and *Candida tropicalis*.

The following data are available, but their clinical significance is unknown.

Voriconazole exhibits *in vitro* minimal inhibitory concentrations (MICs) of 1 µg/mL or less against most (≥90%) isolates of the following microorganisms; however, the safety and effectiveness of Voriconazole in treating clinical infections due to these *Candida* species have not been established in adequate and well-controlled clinical trials:

Candida lusitanae
Candida guilliermondii

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

None

I. Device Description:

The Voriconazole 1µg, BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk utilizes 6-mm disks prepared by impregnating absorbent paper with a known concentration of Voriconazole. Each Voriconazole disk is marked on both sides with the agent (VOR) and drug content (1). Voriconazole 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

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

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 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	Voriconazole	Ciprofloxacin

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

CLSI M2-A9 “Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard.” CLSI M44-A “Method for Antifungal Disk Diffusion Susceptibility Testing Yeasts; Approved Guideline”. 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. The CDRH guidance document “Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs” published October 30, 1996.

L. Test Principle:

BBL™ Sensi-Disc™ utilizes dried filter paper disks impregnated with known concentrations of antifungal agents that are placed onto the test medium surface. The standard method of testing is the Kirby-Bauer method. Discs containing antifungal agents are applied to the surface of Mueller Hinton Agar supplemented with 2% Glucose and 0.5 µg/mL Methylene Blue Dye (GMB) plates that have been 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 antifungal agents in order to determine the agent(s) most suitable for use in antimicrobial therapy. Five colonies of approximately 1mm in diameter from a 24 hour old culture of *Candida* species grown on blood agar or Sabouraud dextrose agar are transferred to 5 ml of a suitable broth medium. The broth is incubated at 35-37° C for 2 to 8 hours until a light to moderate turbidity develops. The final inoculum density should be equivalent to a 0.5 McFarland turbidity standard. The inoculum density may also be standardized photometrically. Within 15 minutes of inoculum preparation, the Mueller-Hinton + GMB agar plate is streaked to obtain an even inoculation. Disks are aseptically placed onto the agar surface with a disk dispenser or sterile forceps to ensure contact with the test surface. Plates are incubated, agar side up, in an ambient air incubator at 35-37° C. Examine the plates after 20-24 hours of incubation. Read at 48 hour only when insufficient growth is observed after 24 hour incubation. After incubation the media is examined, and zones of inhibition around the disks are measured and compared against recognized zone size ranges for the antimicrobial agent being tested. A disk diffusion method for testing *Candida* species was developed and recommended in CLSI M44 Approved Standard document.

M. Performance Characteristics (if/when applicable):

Descriptive characteristics are sufficient for susceptibility test discs, because the drug manufacturer performed several clinical outcome studies enrolling around 595 patients, which were evaluated by CDER to grant approval of Voriconazole. These studies generated the Interpretive Criteria and QC Expected Ranges which the susceptibility tests disc 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):

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 required—Descriptive Characteristics sufficient. *b. Matrix comparison:*
Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

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 in millimeters:

Candida species ≥ 17 mm: Susceptible (S)

Candida species 14-16 mm: Intermediate (I)

Candida species ≤ 13 mm: Resistant (R)

N. 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.