

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

A. 510(k) Number:

k082271

B. Purpose for Submission:

Addition of Fluconazole to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disc

C. Measurand:

Fluconazole 25 µg

D. Type of Test:

Semi-quantitative Antimicrobial Susceptibility Test Disc

E. Applicant:

BD Diagnostic Systems

F. Proprietary and Established Names:

Fluconazole 25 ug BBL™ Sensi-Disc™

G. Regulatory Information:

1. Regulation section:

21 CFR 866.1620

2. Classification:

II

3. Product code:

JTN Susceptibility Test Disc, Antimicrobial

4. Panel:

H. Intended Use:

1. Intended use(s):

BBL™ Sensi-Disc™ Fluconazole Antimicrobial Susceptibility Discs 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 Fluconazole 25 ug, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of pathogens to Fluconazole. The concentration of 25 ug has been shown to be active *in vitro* against most strains of *Candida albicans*, *Candida glabrata* (many strains are intermediately susceptible), *Candida parapsilosis*, and *Candida tropicalis*.

3. Special conditions for use statement(s):

For prescription use only

Isolates of *C. krusei* are assumed to be intrinsically resistant to fluconazole and their zone diameters should not be interpreted using the FDA interpretive criteria.

4. Special instrument requirements:

Not Applicable

I. Device Description:

Fluconazole 25 ug BBL™ Sensi-Disc™ is prepared by impregnating high quality paper accurately with determined amounts of Fluconazole supplied by the drug manufacturer. Each Fluconazole disk is clearly marked on both sides with the agent and drug content. Fluconazole 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. Fluconazole 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):

BBL™ Sensi-Disc™ Antimicrobial Susceptibility test Disks, Ciprofloxacin 5 µg

2. Predicate K number(s):

k874425

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
1. Intended Use	test susceptibility to pathogenic isolates	same
2. Inoculum	pure colonies	same
3. Results	minimum inhibitory concentration (MIC) results based on measurements of zone diameters	
3. Interpretation	categorical interpretations (S-I-R) using the measured zone diameters	same

Differences		
Item	Device	Predicate
1. Test organisms	fungi	bacteria
2. Antibiotic	fluconazole 25 µg	ciprofloxacin 5 µg

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

Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Informational Supplement M44-S2; 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 selected agents are applied to the surface of Mueller Hinton Agar plates, supplemented as needed and inoculated with pure culture 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 agents in order to determine the agent(s) most suitable for use in therapy. The categorical interpretation [susceptible (S), intermediate (I), or resistant (R)] for the organism being tested is made by comparing zone diameters to those found in the approved pharmaceutical package insert.

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:

	Disk Diffusion at 24 hours (Zone Diameters in mm)		
Antimicrobial Agent	Susceptible (S)	Intermediate (I)**	Resistant (R)
Fluconazole*	≥19	15 – 18	≤14

* Isolates of *C. krusei* are assumed to be intrinsically resistant to fluconazole and their MICs and/or zone diameters should not be interpreted using this scale.

** The intermediate category is sometimes called Susceptible-Dose Dependent (SDD) and both categories are equivalent for fluconazole.

N. Proposed Labeling:

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

O. Conclusion:

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