

**510(k) SUMMARY**

KO 82272

**SUBMITTED BY:**

Becton, Dickinson and Company  
7 Loveton Circle  
Sparks, MD 21152  
Phone 410-316-4938  
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**OCT 02 2008**

**CONTACT NAME:**

Janine Matlak, Regulatory Affairs Specialist

**DATE PREPARED:**

August 8, 2008

**DEVICE TRADE NAME:**

Voriconazole 1µg, BBL™ Sensi-Disc™ Antimicrobial  
Susceptibility Test Disks

**DEVICE COMMON NAME:**

Antimicrobial Susceptibility Test Disks

**DEVICE CLASSIFICATION:**

21 CFR§866.1620, Class II (Product Code JTN), Susceptibility  
Test Disks, Antimicrobial

**PREDICATE DEVICE:**

Other BBL™ Sensi-Disc™  
(eg, Ciprofloxacin 5 µg, BBL™ Sensi-Disc™)

**INTENDED USE:**

Antimicrobial Susceptibility Test Disks are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Voriconazole 1µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Voriconazole of a wide range of pathogens, as described in the "Indications for Use" section. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobial manufacturer and received FDA approval under NDA Number 21-266.

**510(k) SUMMARY****Indications for Use:**

Use of Voriconazole 1µg, 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 1µg has been shown to be active *in vitro* against most strains of *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*  
*Candida tropicalis*

**Active In Vitro Against:**

*Candida lusitanae*  
*Candida guilliermondii*

**DEVICE DESCRIPTION:**

Voriconazole 1µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Voriconazole supplied by the drug manufacturer. Each Voriconazole disk is clearly marked on both sides with the agent and drug content. 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. Voriconazole 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 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.

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the Clinical and Laboratory Standards Institute (CLSI) [Formerly National Committee for Clinical Laboratory Standards (NCCLS)] and is periodically updated.

**DEVICE 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 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 agents in order to determine the agent(s) most suitable for use in therapy. The categorical interpretation [susceptible (S), susceptible-dose dependent (S-DD), or resistant (R)] for the organism being tested is made by comparing zone diameters to those found in the approved pharmaceutical package insert.

**DEVICE COMPARISON:**

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks – Voriconazole 1µg is similar to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- Both methods are for susceptibility testing using paper disks impregnated with an agent.
- Both methods are intended to test susceptibility to pathogenic isolates.
- Both methods provide the user with minimum inhibitory concentration (MIC) results based on measurements of zone diameters.
- Both methods require the user to determine categorical interpretations using the measured zone diameters against CLSI Approved Standards.
- Both methods use pure cultures of isolates.

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Voriconazole 1µg differs from the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Voriconazole 1µg is a susceptibility test that uses disks impregnated with Voriconazole at a concentration of 1µg while the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg is a susceptibility test that uses disks impregnated with Ciprofloxacin at a concentration of 5 µg.
- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk – Voriconazole 1 µg is a susceptibility test used to test a different battery of isolates than the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Ciprofloxacin 5 µg.

**SUBSTANTIAL EQUIVALENCE TESTING DATA:**

See the Voriconazole drug package insert, “Susceptibility Testing Methods: Diffusion Techniques” (Appendix 1).

## 1.0 INTRODUCTION

Becton, Dickinson and Company, BD Diagnostic Systems, is submitting this premarket notification in accordance with 21CFR§807.81 for a device being introduced into commercial distribution for the first time.

BD Diagnostic Systems is adding Voriconazole 1µg to the currently available BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks product. Ciprofloxacin (5 µg), was added to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks product line when FDA clearance was granted per premarket notification #K874425. Disks containing Ciprofloxacin are being used as one example of this product line and are the predicate device for this submission.

### 1.1 Intended Use

Antimicrobial Susceptibility Test Disks are used for semi-quantitative in vitro susceptibility testing by standardized agar diffusion test procedures. Voriconazole 1µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Voriconazole of a wide range of pathogens, as described under Indications for Use (Section 1.2). Zone diameters used for interpretation of tests, including control organism limits, were determined by the antimicrobial manufacturer, and received FDA approval under NDA 21-266.

## 1.2 Indications for Use

Use of Voriconazole 1µg, 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 1µg has been shown to be active *in vitro* against most strains of *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*  
*Candida tropicalis*

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

*Candida lusitanae*  
*Candida guilliermondii*

## 2.0 DEVICE INFORMATION

### 2.1 Device Description

Voriconazole 1µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Voriconazole supplied by the drug manufacturer. Each Voriconazole disk is clearly marked on both sides with the agent and drug content. 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. Voriconazole 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 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.<sup>1,2</sup>

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA)<sup>3</sup> and the World Health Organization (WHO).<sup>4,5</sup> The procedure was adopted as a consensus standard by the Clinical Laboratory Standard Institute (CLSI) [Formerly National Committee for Clinical Laboratory Standards (NCCLS)] and is periodically updated.<sup>6,7,8</sup>

<sup>1</sup> Bauer, A.W., W.M.M. Kirby, J.C. Sherris, and M. Turck. 1966. Antibiotic susceptibility testing by a standardized single disk method. *Am. J. Clin. Pathol.* 45:493-496.

<sup>2</sup> Ryan, K.J., F.D. Schoenknecht, and W.M.M. Kirby. 1970. Disc sensitivity testing. *Hospital Practice* 5:91-100.

<sup>3</sup> Federal Register. 1972. Rules and regulations. Antibiotic susceptibility discs. *Fed. Regist.* 37:20525-20529. Erratum, 38:2756, 1973.

<sup>4</sup> Ericsson, H.M., and J.C. Sherris. 1971. Antibiotic sensitivity testing. Report of an international collaborative study. *Acta Pathol. Microbiol. Scand. Sec. B. Suppl.* 217:1-90.

<sup>5</sup> World Health Organization Expert Committee on Biological Standardization. 1977. Technical report series 610. W.H.O., Geneva.

<sup>6</sup> Clinical and Laboratory Standards Institute (Formerly NCCLS). 2006. Approved standard M2-A9. Performance standards for antimicrobial disk susceptibility tests, 9<sup>th</sup> ed. CLSI, Wayne, Pa.

<sup>7</sup> Clinical and Laboratory Standards Institute (Formerly NCCLS). 2008. M100-S18 (M2). Performance Standards for Antimicrobial Susceptibility Testing; Eighteenth Informational Supplement. CLSI, Wayne, Pa.

<sup>8</sup> Clinical and Laboratory Standards Institute (Formerly NCCLS). 2004. M44-A. Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline. CLSI, Wayne, Pa.

## 2.2 Device 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 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 agents in order to determine the agent(s) most suitable for use in therapy. The categorical interpretation [susceptible (S), susceptible-dose dependent (S-DD), or resistant (R)] for the organism being tested is made by comparing zone diameters to those found in the approved pharmaceutical package insert.

### 3.0 DEVICE COMPARISON

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Voriconazole 1µg as described in this submission, is substantially equivalent<sup>1</sup> to a legally marketed device for the susceptibility testing by agar disk diffusion method. The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Voriconazole 1µg is substantially equivalent to all of the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks manufactured and marketed by Becton, Dickinson and Company for over 30 years. Specifically, the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Voriconazole 1µg is substantially equivalent to BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Ciprofloxacin 5 µg (K874425). The Voriconazole 1µg BBL™ Sensi-Disc™ has the same technological characteristics as its predicate, Ciprofloxacin 5 µg, BBL™ Sensi-Disc™.

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Voriconazole 1µg is similar to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk – Ciprofloxacin 5 µg in that:

- Both methods are for susceptibility testing using paper disks impregnated with an agent.
- Both methods are intended to test susceptibility to pathogenic isolates.
- Both methods provide the user with minimum inhibitory concentration (MIC) results based on measurements of zone diameters.
- Both methods require the user to determine categorical interpretations using the measured zone diameters against CLSI Approved Standards.
- Both methods use pure cultures of isolates.

The BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Voriconazole 1µg differs from the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Voriconazole 1µg is a susceptibility test that uses disks impregnated with Voriconazole at a concentration of 1µg while the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg is a susceptibility test that uses disks impregnated with Ciprofloxacin at a concentration of 5 µg.
- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk – Voriconazole 1 µg is a susceptibility test used to test a different battery of isolates than the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Ciprofloxacin 5 µg.

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<sup>1</sup> The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the U.S. Patent Laws or their application by the courts.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Becton, Dickinson and Company  
c/o Ms. Janine Matlak  
Regulatory Affairs Specialist  
7 Loveton Circle  
Sparks, MD 21152

OCT 02 2008

Re: k082272  
Trade/Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks,  
Voriconazole 1µg  
Regulation Number: 21 CFR§ 866.1620  
Regulation Name: Antimicrobial Susceptibility Test Disc.  
Regulatory Class: Class II  
Product Code: JTN  
Dated: August 8, 2008  
Received: August 11, 2008

Dear Ms. Matlak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

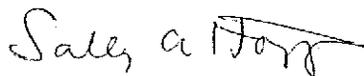
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.  
Director  
Division of Microbiology Devices  
Office of *In Vitro* Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082272

Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Voriconazole 1µg

Indications for Use:

Use of Voriconazole 1µg, 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 1µg has been shown to be active *in vitro* against most strains of *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*
- Candida tropicalis*

Active In Vitro Against:

- Candida lusitanae*
- Candida guilliermondii*

Prescription Use   ✓    
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Freddie W. Poole  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K08 2272