



Food and Drug Administration
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October 13, 2015

BECTON, DICKINSON AND COMPANY
LAURA STEWART
REGULATORY AFFAIRS SPECIALIST
7 LOVETON CIRCLE
SPARKS MD 21152-0999

Re: K152516

Trade/Device Name: BD BBL Sensi-disc Ceftazidime Avibactam (30/20ug), Antimicrobial
Susceptibility Test Disks

Regulation Number: 21 CFR 866.1620

Regulation Name: Antimicrobial susceptibility test disc

Regulatory Class: II

Product Code: JTN

Dated: September 1, 2015

Received: September 3, 2015

Dear Ms. Stewart:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Ribhi Shawar -S

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152516

Device Name

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

Indications for Use (Describe)

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 antimicrobial.

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

SUBMITTED BY: Becton, Dickinson and Company
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Sparks, MD 21152
Phone 410-316-4435
Fax: 410-316-4188

CONTACT NAME: Laura Stewart, Regulatory Affairs Specialist

DATE PREPARED: September 1, 2015

DEVICE TRADE NAME: BD BBL™ Sensi-Disc™ Ceftazidime avibactam (30/20µg), Antimicrobial Susceptibility Test Discs

DEVICE COMMON NAME: Antimicrobial Susceptibility Test Discs

DEVICE CLASSIFICATION: 21 CFR§866.1620, Class II (Product Code JTN), Susceptibility Test Discs, Antimicrobial

PREDICATE DEVICE: Other BD BBL™ Sensi-Disc™ (e.g., Ciprofloxacin 5 µg, BD BBL™ Sensi-Disc™)

INTENDED USE:

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 antimicrobial manufacturer and received FDA approval under NDA Number 206494.

510(k) SUMMARY

Indications 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 antimicrobial.

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

DEVICE DESCRIPTION:

BD BBL™ Sensi-Disc™ Ceftazidime avibactam (30/20µg), Antimicrobial Susceptibility Test Discs are 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 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:

Discs 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. 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").

DEVICE COMPARISON:

The BD BBL™ Sensi-Disc™ Ceftazidime avibactam (30/20µg) is similar to the BD BBL™ Sensi-Disc™ Ciprofloxacin, 5µg in that:

- Both methods are for antimicrobial susceptibility testing using paper discs impregnated with an antimicrobial agent.
- Both methods have the same intended use.
- Both methods provide the user with antimicrobial minimum inhibitory concentration (MIC) results based on measurements of zone diameters.
- Both methods require the user to determine categorical interpretations (S/I/R) using the measured zone diameters against CLSI/NCCLS Approved Standards M2 and M100.
- Both methods use pure cultures of bacterial isolates.

The BD BBL™ Sensi-Disc™ Ceftazidime avibactam (30/20µg) differs from the BD BBL™ Sensi-Disc™ Ciprofloxacin, 5µg in that:

- BD BBL™ Sensi-Disc™ Ceftazidime avibactam (30/20µg) is a susceptibility test that uses discs impregnated with the antimicrobics Ceftazidime at a concentration of 30µg and Avibactam at a concentration of 20µg while the BD BBL™ Sensi-Disc™ Ciprofloxacin, 5µg is a susceptibility test that uses discs impregnated with the antimicrobial Ciprofloxacin at a concentration of 5µg.
- BD BBL™ Sensi-Disc™ Ceftazidime avibactam (30/20µg) is a susceptibility test used to test a different battery of microorganisms than the BD BBL™ Sensi-Disc™ Ciprofloxacin, 5µg.

SUBSTANTIAL EQUIVALENCE TESTING DATA:

See the Ceftazidime avibactam drug package insert, "Microbiology". Shelf life (stability data) for the drug is being collected and will be maintained on file at BD as indicated in the guidance document.