MAR 29 2010

510(k) SUMMARY

Indications for Use:

Use of Telavancin 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 Telavancin. 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 antimicrobic.

Active *In Vitro* and in Clinical Infections Against:

Facultative Gram-positive Microorganisms
Staphylococcus aureus (including methicillin-resistant isolates)
Streptococcus pyogenes
Enterococcus faecalis (vancomycin-susceptible isolates only)
Streptococcus agalactiae
Streptococcus anginosus group (includes *S. anginosus, S. intermedius* and *S. constellatus*)

Active *In Vitro* Against:

Facultative Gram-positive Microorganisms
Enterococcus faecium (vancomycin-susceptible isolates only)
Staphylococcus haemolyticus
Streptococcus dysgalactaie subsp. *equisimilis*
Staphylococcus epidermidis

DEVICE DESCRIPTION:

Telavancin30µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Telavancin supplied by the drug manufacturer. Each Telavancin disk is clearly marked on both sides with the agent and drug content. Telavancin 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. Telavancin 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 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 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 BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks – Telavancin 30µg is similar to the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks – Ciprofloxacin 5 µg in that:

- Both methods are for antimicrobial susceptibility testing using paper disks impregnated with an antimicrobial agent.
- Both methods have the same intended use.
- Both methods provide the user with antimicrobic 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 BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Telavancin 30µg differs from the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg in that:

- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Telavancin 30µg is a susceptibility test that uses disks impregnated with the antimicrobic Telavancin at a concentration of 30µg while the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks - Ciprofloxacin 5 µg is a susceptibility test that uses disks impregnated with the antimicrobic Ciprofloxacin at a concentration of 5 µg.
- BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk – Telavancin 30 µg is a susceptibility test used to test a different battery of microorganisms than the BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disk - Ciprofloxacin 5 µg.

SUBSTANTIAL EQUIVALENCE TESTING DATA:

See the Telavancin drug package insert, "Microbiology".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Ms. Janine Matlak Spafford
Becton Dickinson and Company
7 Loveton Circle. MC 614
Sparks, MD 21152

MAR 29 2010

Re: K100722
Trade/Device Name: BBL™Sensi-Disc™ Telavancin 30µg
Regulation Number: 21 CFR 866.1620
Regulation Name: Antimicrobial Susceptibility Test Disc
Regulatory Class: Class II
Product Code: JTN
Dated: March 12, 2010
Received: March 15, 2010

Dear Ms. Spafford:

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 Part 801); 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 regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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): K100722

Device Name: BBL™ Sensi-Disc™ Antimicrobial Susceptibility Test Disks, Telavancin30µg

Indications for Use:

Use of Telavancin 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 Telavancin. 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 antimicrobic.

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Staphylococcus haemolyticus
Streptococcus dysgalactaie subsp. *equisimilis*
Staphylococcus epidermidis

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)

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K100722