July 1, 2019

Becton, Dickinson and Company
Laura Stewart
Regulatory Affairs Project Manager
7 Loveton Circle, MC 694
Sparks, Maryland 21152

Re: K190905
Trade/Device Name: BD Phoenix Automated Microbiology System - GN Ceftaroline (0.0156-4 µg/mL)
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: Class II
Product Code: LON
Dated: April 5, 2019
Received: April 8, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Uwe Scherf, M. Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

5. 510(k) Summary

BD Phoenix™ Automated Microbiology System – GN Ceftaroline (0.0156-4 µg/mL)

Summary Preparation Date:

4/5/2019

Submitted by:

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152

Contact:

Laura Stewart
Regulatory Affairs Project Manager
Tel: 410-316-4435
Fax: 410-316-4188
Email: laura.stewart@bd.com

Proprietary Names:
BD Phoenix™ Automated Microbiology System – GN Ceftaroline (0.0.156-4 µg/mL)

Common Names:
Antimicrobial susceptibility test system-short incubation

Regulatory Information

Regulation section:
21 CFR 866.1645
Fully automated short-term incubation cycle antimicrobial susceptibility system.

Classification:
Class II

Review Panel:
Microbiology

Product Code:
LON

Predicate Device
BD Phoenix™ Automated Microbiology System – GN Tigecycline (0.25-16 µg/mL)
[510(k) K132909]

Device Establishment

Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152
Registration Number: 1119779

Performance Standards

Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems. August 28, 2009.

CLSI M100 27th Edition, Performance Standards For Antimicrobial Susceptibility Testing. (In Vitro Diagnostics). Recognition Number 7-271.

CLSI M07-A10, Methods For Dilution Antimicrobial Susceptibility Tests For Bacteria That Grow Aerobically; Approved Standard - Tenth Edition. (In Vitro Diagnostics). Recognition Number 7-254.

Intended Use

The BD Phoenix™ Automated Microbiology System is intended for the *in vitro* rapid identification (ID) and quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most Gram negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and non-*Enterobacteriaceae*.

Special Conditions for Use Statement: For prescription use.

Special Instrument Requirements: BD Phoenix™ Automated Microbiology System

Device Description

The BD Phoenix™ Automated Microbiology System (Phoenix System) is an automated system for the rapid identification (ID) and antimicrobial susceptibility testing (AST) of clinically relevant bacterial isolates. The system includes the following components:

- BD Phoenix instrument and software.
- BD Phoenix panels containing biochemicals for organism ID testing and antimicrobial agents for AST determinations.
- BD Phoenix ID Broth used for performing ID tests and preparing AST Broth inoculum.
- BD Phoenix AST Broth used for performing AST tests only.
- BD Phoenix AST Indicator solution added to the AST Broth to aid in bacterial growth determination.

The Phoenix panel is a sealed and self-inoculating molded polystyrene tray with 136 micro-wells containing dried reagents. Organisms for susceptibility testing must be a pure culture and preliminarily identified as a Gram-negative or Gram-positive isolate. Phoenix panels are inoculated with a specified organism density and placed into the instrument. Inoculum for use with the Phoenix system may be prepared either manually or may be automated using the BD Phoenix™ AP System.

The Phoenix AST method is a broth based microdilution test. The Phoenix System utilizes a redox indicator for the detection of organism growth in the presence of an antimicrobial agent. Measurements of changes to the indicator as well as bacterial turbidity are used in the determination of bacterial growth. Each AST panel configuration contains several antimicrobial agents with a wide range of two-fold doubling dilution concentrations.

The instrument houses the panels where they are continuously incubated at a nominal temperature of 35 °C ± 1 °C. The instrument takes readings of the panels every 20 minutes. The readings are interpreted to give an identification of the isolate, minimum inhibitory concentration (MIC) values and category interpretations, S, I, R or N (susceptible, intermediate, resistant or not susceptible).

Device Comparison

The BD Phoenix™ Automated Microbiology System demonstrated substantially equivalent performance for inoculum prepared manually and inoculum prepared with the BD Phoenix™ AP instrument when compared with the CLSI reference broth microdilution method. This premarket notification provides data supporting the use of the BD Phoenix™ Automated Microbiology System Gram negative ID/AST or AST only Phoenix panels with this antimicrobial agent.

Summary of Substantial Equivalence[1] Testing

The BD Phoenix™ Automated Microbiology System has demonstrated substantially equivalent performance when compared to the CLSI reference broth microdilution method (AST panels prepared according to CLSI M07). The system has been evaluated as defined in the FDA guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", August 28, 2009. Shelf life (stability data) for the drug is being collected and will be maintained on file at BD as indicated in the guidance document.

Analytical Performance

Reproducibility

Intra- and inter-site reproducibility of this antimicrobial agent in the BD Phoenix System was evaluated at three sites using a panel of Gram-negative isolates. Each site tested the isolates in triplicate on three different days using one lot of Gram Negative Phoenix panels containing this antimicrobial agent and associated reagents.

The results of the study demonstrate that for this antimicrobial agent and the Gram-negative organisms tested there was an overall reproducibility across test sites of greater than 95% (± 1 dilution) agreement when compared to the test mode.

[1] 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 US Patent Laws or their application by the courts.

Clinical Performance Studies

Clinical, stock and challenge isolates were tested across multiple geographically diverse sites across the United States to demonstrate the performance of the Phoenix antimicrobial susceptibility test with a Gram Negative Phoenix Panel containing this antimicrobial agent. Phoenix System results for Challenge set isolates were compared to the expected results. Phoenix System results for clinical isolates were compared to the results obtained from the CLSI reference broth microdilution method.

The performance of the Phoenix System was assessed by calculating Essential Agreement (EA) and Category Agreement (CA) to expected/reference results for all isolates tested. Essential Agreement (EA) occurs when the BD Phoenix™ Automated Microbiology System agrees exactly or within ± one two-fold dilution to the reference result. Category Agreement (CA) occurs when the BD Phoenix™ Automated Microbiology System agrees with the reference method with respect to the FDA categorical interpretive criteria (susceptible, intermediate, resistant or not susceptible).

The following table summarizes the performance for Clinical and Challenge isolates tested in this study.

Performance of BD Phoenix System for Ceftolozane/tazobactam with GN Organisms

Antimicrobial	Concentration	EA (n)	EA (%)	CA (n)	CA (%)
Ceftaroline	0.0156-4 µg/mL	987	94.6	987	96.1

To address testing of non-indicated species, the sponsor included the following statement in the Precautions section of the device labeling:

> *Per the FDA-Recognized Susceptibility Test Interpretive Criteria Website, the safety and efficacy of antimicrobial drugs, for which antimicrobial susceptibility is tested by this AST device, may or may not have been established in adequate and well-controlled clinical trials for treating clinical infections due to microorganisms outside of those found in the indications and usage in the drug label. The clinical significance of susceptibility information in those instances is unknown. The approved labeling for specific antimicrobial drugs provides the uses for which the antimicrobial drug is approved.*

Conclusions Drawn from Substantial Equivalence Studies

The data collected from the substantial equivalence studies demonstrate that testing on the BD Phoenix™ Automated Microbiology System with this antimicrobial agent is substantially equivalent as outlined in the FDA draft guidance document, "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA", August 28, 2009. Technological characteristics of this system are substantially equivalent to those used in the BD Phoenix™ Automated Microbiology System – GN Tigecycline (0.25-16 µg/mL), which received approval by the FDA under 510(k) number K132909, February 14, 2014.