K040099

MAR 1 9 2004

510(K) SUMMARY

SUBMITTED BY: Becton, Dickinson and Company
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CONTACT NAME: Monica E. Giguere,
Regulatory Affairs Specialist

DATE PREPARED: January 16, 2004

DEVICE TRADE NAME: BD Phoenix™ Automated Microbiology System – Modifications to Phoenix System Software through Version 4.0 and BDXpert System resident on the EpiCenter System

DEVICE COMMON NAME: Antimicrobial susceptibility test system-short incubation

DEVICE CLASSIFICATION: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility Device, 21 CFR 866.1645

PREDICATE DEVICES: BD Phoenix™ Automated Microbiology System with Gatifloxacin (K020321, May 23, 2002), Ofloxacin (K020323, April 14, 2002), and Levofloxacin (K020322, March 27, 2002).

INTENDED USE: The BD Phoenix™ Automated Microbiology System is intended for the rapid identification and *in vitro* antimicrobial susceptibility testing of isolates from pure culture of most aerobic and facultative anaerobic Gram-negative and Gram-positive bacteria of human origin.

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 or 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.

Software incorporated into the BD Phoenix™ Automated Microbiology System provides the user with the ability to process Phoenix ID and/or Phoenix AST panels in a walk-away fashion. The software allows for the establishment of a panel test, automated/unattended testing of the panel and the ability to review the panel results. In order to accomplish the overall general purpose of the instrument, the software provides users with the ability to interact with the instrument, when necessary to facilitate the testing that they require. The Phoenix software includes the BDXpert System which is a collection of rules intended to evaluate results for specific organism-drug combinations.

The BDXpert System that is resident on the EpiCenter System is basically the same Expert system that exists on the Phoenix System. However, the BDXpert System utilizes additional information, such as specimen site, to provide the user with a more refined SIR interpretation.

The Phoenix software was developed and tested according to its Software Development Plan and Software Verification and Validation Plan. The software test results demonstrated that the software operated in accordance to the software specifications

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. For each isolate, an inoculation equivalent to a 0.5 McFarland standard is prepared in Phoenix ID broth.

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. 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, or R (sensitive, intermediate, or resistant).

DEVICE COMPARISON:

The modifications to Phoenix Instrument Software through Version 4.0 and the BDXpert System resident on the EpiCenter System, as described in this submission, are substantially equivalent[1] to BD Phoenix™ Automated Microbiology System with Gatifloxacin (K020321, May 23, 2002), Ofloxacin (K020323, April 14, 2002), and Levofloxacin (K020322, March 27, 2002) (also referred to as previously submitted Phoenix Instrument software).

[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.

The modifications to Phoenix Instrument Software through Version 4.0 and the BD Phoenix™ Automated Microbiology System (K020321, K020323, and K020322) are similar in that they have the same intended use and automatically provide the user with antimicrobic minimum inhibitory concentration (MIC) results and SIR interpretations. The modifications to Phoenix Instrument Software through Version 4.0 and the BD Phoenix™ Automated Microbiology System (K020321, K020323, and K020322) are different because of new features introduced into the software as described in this submission.

The BDXpert System resident on the EpiCenter System is similar to the BD Phoenix™ Automated Microbiology System (K020321, K020323, and K020322) in that both automatically provide the user with reports containing antimicrobic minimum inhibitory concentration (MIC) results and SIR interpretations. The BDXpert System resident on the EpiCenter System is different from the BD Phoenix™ Automated Microbiology System (K020321, K020323, and K020322) in that the BDXpert System resident on the EpiCenter System in itself does not actually perform the analysis of the test panels. The BD Phoenix™ Automated Microbiology System actually performs the test analysis. Also the BDXpert System resident on the EpiCenter System utilizes additional information, such as specimen type, to determine the BDXpert SIR interpretation. The BD Phoenix™ Automated Microbiology System does not use this information when determining the BDXpert SIR interpretation.

Although there are some differences between the BD Phoenix™ Automated Microbiology System and the reference method and predicate device, these differences do not raise new issues of safety and effectiveness.

In review of previous 510(k) premarket notifications for the BD Phoenix™ Automated Microbiology System with Gatifloxacin (K020321, May 23, 2002), with Ofloxacin (K020323, April 14, 2002), and with Levofloxacin (K020322, March 27, 2002) the Food and Drug Administration (FDA) has determined the Phoenix system to be substantially equivalent to devices market

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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MAR 19 2004

Ms. Monica E. Giguere
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BD Diagnostics Systems
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Sparks, MD 21152

Re: k040099
Trade/Device Name: BD Phoenix™ Automated Microbiology Systems
Modifications to Phoenix System Software through Version 4.0
and higher and BDXpert system resident on the EpiCenter System
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial
Susceptibility Devices
Regulatory Class: Class II
Product Code: LON
Dated: January 16, 2004
Received: January 20, 2004

Dear Ms. Giguere:

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.

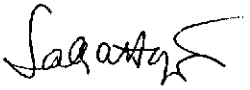
If your device is classified (see above) into either class II (Special Controls) o. class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish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

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
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Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K040099

Device Name: BD Phoenix™ Automated Microbiology System - Modifications to Phoenix System Software through Version 4.0 and higher and BDXpert system resident on the EpiCenter System

Indications for Use:

The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration (MIC) of most gram-negative aerobic and facultative anaerobic bacteria isolates from pure culture for *Enterobacteriaceae* and Non-*Enterobacteriaceae* and most gram-positive bacteria isolates from pure culture belonging to the genera *Staphylococcus* and *Enterococcus*.

This premarket notification is for the Modifications to Phoenix System Software and for the BDXpert System resident on the EpiCenter System.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 807 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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040099