510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE AND INSTRUMENT TEMPLATE

A. 510(k) Number:
k040099

B. Analyte:
Software for the BDXpert System resident on the EpiCenter System

C. Type of Test:
Software for AST reading and interpretation

D. Applicant:
Becton, Dickinson and Company

E. Proprietary and Established Names:
BD Phoenix™ Automated Microbiology System-Modifications to Phoenix™ System Software and for the BDXpert System resident on the EpiCenter System

F. Regulatory Information:

1. Regulation section:
   866.1645
2. Classification:
   Class II
3. Product Code:
   LON
4. Panel:
   83 Microbiology

G. Intended Use:

1. Intended use(s):
   The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration of gram-negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and Non-*Enterobacteriaceae* and gram-positive bacteria belonging to the genera *Staphylococcus* and *Enterococcus*.

2. Indication(s) for use:
   This is for the Modifications to Phoenix™ System Software and for the BDXpert System resident on the EpiCenter System
3. Special condition for use statement(s):

Prescription Use

4. Special instrument Requirements:
   Not applicable

H. 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 of AST determinations, BD Phoenix™ ID broth used for performing organism ID testing and preparing AST Broth inoculum, BD Phoenix™ AST Broth used for performing AST tests only, and BD Phoenix™ AST indicator solution added to the AST Broth to aid in bacterial growth determination.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Previously submitted software Phoenix instrumentation such as with gatifloxacin
2. Predicate K number(s):
   K020321
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	The BD Phoenix™ Automated Microbiology System is intended for *in vitro* quantitative determination of antimicrobial susceptibility by minimal inhibitory concentration of gram-negative aerobic and facultative anaerobic bacteria belonging to the family *Enterobacteriaceae* and Non-*Enterobacteriaceae* and gram-positive bacteria belonging to the genera *Staphylococcus* and *Enterococcus*	same
results	SIR and MIC reported	same

Differences		
Item	**Device**	**Predicate**
Test analysis	BDXpert System resident on the EpiCenter does not perform analysis	Performed by BD Phoenix™ automated Microbiology System
Use of additional information	Uses specimen type in determining interpretation	Does not use this information

Resistant marker feature	Uses results from completed antibiotics to infer interpretations on other antibiotics when applicable (as recommended by NCCLS etc.)	All results are read at the completed time for each antibiotic

J. Standard/Guidance Document Referenced (if applicable):

NCCLS M7 (M100-S14) "Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard" and the "Guidance for the Content of PreMarket Submissions for Software in Medical Devices".

K. Test Principle:

The system employs conventional, colorimetric, fluorogenic and chromogenic substrates to identify the genus and species of the isolate. The AST portion of the Phoenix™ System is a broth based microdilution method that utilizes a redox indicator (colorimetric oxidation-reduction) to enhance detection of organism growth. The MIC is determined by comparing growth in wells containing serial two-fold dilutions of an antibiotic to the growth in "growth control wells" which contain no antibiotic.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    - *a. Precision/Reproducibility:*
      Not applicable
    - *b. Linearity/assay reportable range:*
      Not applicable
    - *c. Traceability (controls, calibrators, or method):*
      Not applicable
    - *d. Detection limit:*
      Not applicable
    - *e. Analytical specificity:*
      Not applicable
    - *f. Assay cut-off:*
      Not applicable
2. Comparison studies:
    - *a. Method comparison with predicate device:*
      Not applicable
    - *b. Matrix comparison:*
      Not applicable
3. Clinical studies:
    - *a. Clinical sensitivity:*
      Not applicable
    - *b. Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a and b are not applicable):
Not applicable

4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   Not applicable

M. Instrument Name:

BD Phoenix™ Automated Microbiology System

N. System Descriptions:

1. Modes of Operation:
   Not Applicable
2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
Yes __X_____ or No _____

3. Sample Identification:
   Not applicable
4. Specimen Sampling and Handling:
   Not applicable
5. Assay Types:
   Not applicable
6. Reaction Types:
   Not applicable
7. Calibration:
   Not applicable
8. Quality Control:
   Not applicable

O. Other Supportive Instrument Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of the SE Determination Decision Summary.

Not applicable

P. Conclusion:

The information contained within this submission is sufficient to meet the software concerns as described in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and it is recommended that, from a software standpoint, this device be considered substantially equivalent.