SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K250344

B Applicant

Becton, Dickinson and Company

C Proprietary and Established Names

BD Phoenix Automated Microbiology System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LON	Class II	21 CFR 866.1645 - Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System	MI - Microbiology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own **CLASS II** device requiring a 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS CHANGED** along with the proposed labeling which includes user manuals. Labeling changes are considered minor and do not affect the intended use/indications for use of the original or modified device.

   The **changes** in the Indications for Use statement of the modified device (K250344) aim to:

   a) Apply minor clarifying changes to the text to simplify the language and remove redundancies.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   Changes were made to the BDXpert System to:

   a) Allow for connectivity to the BD Synapsys Informatics Solution and

   b) Add utility to BDXpert that codifies functionality previously created by customers using custom rules**.**

   The new configuration of BDXpert is referred to as BDXpert 2.0, which is a separate product to BDXpert on standalone Phoenix and on EpiCenter (referred to as Legacy BDXpert).

   The device **modifications** under K250344 are only applicable to the BD Phoenix M50 Automated Microbiology System Instrument.

   The **changes** in the labeling of the modified device (K250344) aim to provide the End User/Customer with a set of updated operational documents (i.e,, BDXpert User's Manual, BD Phoenix M50 Instrument User's Manual, and Synapsys User's Manual).

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. A Design Control Activities Summary which includes:

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.