

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

A. 510(k) Number:

k070346

B. Analyte:

Software for the LabPro Alert_{EX} Data Management System Software, version 3.0 and MicroScan® instruments (e.g., WalkAway *SI*, autoSCAN-4)

C. Type of Test:

Software for AST reading and interpretation

D. Applicant:

Dade Behring Inc.

E. Proprietary and Established Names:

Dade Behring LabPro Alert_{EX} Software System

F. Regulatory Information:

1. Regulation section:
21 CFR 866. 1645
2. Classification:
Class II
3. Product Code:
LON
4. Panel:
83 Microbiology

G. Intended Use:

1. Intended use:

The Dade Behring LabPro Alert_{EX} Software System is intended for use with the LabPro Alert_{EX} Data Management System Software, version 3.0 and MicroScan® instruments (e.g., WalkAway *SI*, autoSCAN-4)

2. Indication(s) for Use:

The Alert_{EX} Software system is indicated to notify the user of unusual conditions, or out-of-range results that may warrant further analysis or action,

and/or provide the user with the ability to change organism identification and/or antibiotic susceptibility test interpretations.

3. Special condition for use statement(s):

Prescription Use

4. Special instrument Requirements:

Not applicable

H. Device Description:

The Dade Behring LabPro Data Management System is a Windows based software program used to manage data from MicroScan Instruments or manually entered microbiology test results.

I. Substantial Equivalence Information:

1. Predicate device name(s):

BDXpert System resident on the EpiCenter System

2. Predicate K number(s):

k040099

3. Comparison with predicate:

DEVICE	PREDICATE
A. Similarities	
Dade Behring LabPro Alert _{EX} Software System does not perform test analysis	BD Xpert System resident on the Epicenter does not perform test analysis
Utilize additional information, such as specimen source, to provide the user with a more refined AST interpretation	Utilize additional information, such as specimen source, to provide the user with a more refined AST interpretation
Provide similar added functionality and the ability to change AST interpretations	Provide similar added functionality and the ability to change AST interpretations
SIR and MIC reported	SIR and MIC reported

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

Not Applicable

K. Test Principle:

The Dade Behring LabPro Alert_{EX} Software is a rule-based software application within the LabPro Data Management System Software. The Alert_{EX} Software analyzes MicroScan microbial identification (ID) and antimicrobial agent susceptibility tests (AST) or other parameters (e.g. patient ID, institution, source) against a series of rules.

When panels are read on a MicroScan Instrument, entered manually, or when editing stored patient results, the software compares processed test results against rules and conditions.

The LabPro Alert_{EX} Software is provided to the MicroScan customers in a pre-configured condition with rules pre-defined based upon standard microbiology references. These rules are defined in a table which list susceptibility and ID patterns known to be unusual. Through customization the user may inactivate the pre-configured rules, but the user cannot edit the pre-configured rules. Additionally, user-defined rules may be added to the system to provide alert messages for results (e.g. previous isolation of a resistant organism from a particular patient, address specific physicians, locations, specimen sources or biochemical reactions.)

The LabPro Alert_{EX} will add the capability to change organism ID, and/or generate AST interpretations based on defined parameters utilizing standard microbiology references. The preconfigured alert rules with ID and AST actions are inactive upon installation and must be activated by the user through customization.

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 (functional sensitivity):*

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

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

M. Instrument Name:

Microscan instruments

N. System Descriptions:

1. Modes of Operation:

Not applicable

2. Software:

The firm provided their level of concern and the supporting rationale of moderate. As recommended in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the following was reviewed and found acceptable: Level of Concern, Software Description, Device Hazard Analysis, Software Requirement Specification (SRS), Architectural Design Chart, Software Design Specification, Traceability, Analysis, Development Life cycle, Verification and Validation Testing, Revision Level History, Unresolved Anomalies (Defects), and Release Version Number.

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.