



510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION DECISION SUMMARY

I Background Information:

A 510(k) Number

K201405

B Applicant

Beckman Coulter Inc.

C Proprietary and Established Names

LabPro Data Management 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 Submission/Device Overview:

A Purpose for Submission:

To obtain a substantial equivalence determination for a new version of LabPro Data Management System

B Type of Test:

LabPro Data Management System.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

LabPro Data Management System is a Microsoft Windows based software program and is intended to manage both microbial identification (ID) and antimicrobial agent susceptibility testing (AST) data generated from Beckman Coulter instruments or manually entered microbiology test results, for use by trained laboratory personnel.

LabPro AlertEx is a functional subset of the LabPro Data Management System that analyzes Beckman Coulter ID and AST data, or other pre-defined parameters, against a series of established rules/ alerts and notifies the user of unusual, and/or critical conditions, which may warrant further analysis or action.

LabPro-MBT software is a functional subset of the LabPro Data Management System intended to electronically transfer and display organism identifications from the Bruker MALDI BioTyper System to the LabPro Data Management System. LabPro-MBT software is a device that is intended to electronically transfer medical device data, without controlling or altering the functions or parameters of any connected medical devices.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:**A Device Description:**

The proposed LabPro Data Management System (LPDMS) software device is a system intended to be used in laboratory settings by trained personnel to manage both microbial identification (ID) and antimicrobial agent susceptibility testing (AST) data generated from Beckman Coulter instruments, manually entered data and/or data from select third party microbiology instruments.

The LPDMS consists of two functional subsets. The first subset is The LabPro AlertEx that analyzes Beckman Coulter ID and AST data against a series of established rules/alerts and notifies the laboratory user of unusual, and/or critical conditions. The second subset is the LabPro MBT software that allows for transfer and display of organism identifications from the Bruker MALDI BioTyper System to the proposed LabPro Data Management System.

B Instrument Description Information:**1. Instrument Name:**

LabPro Data Management System (LPDMS) software

2. Specimen Identification:

Microbial identification (ID) and antimicrobial agent susceptibility testing (AST)

3. Specimen Sampling and Handling: N/A

4. Calibration: N/A

5. Quality Control: N/A

V Substantial Equivalence Information:

A Predicate Device Name(s):

Dade Behring Labpro Alert Software System

B Predicate 510(k) Number(s):

K070346

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>Device:</u> <u>K201405</u>	<u>Predicate:</u> <u>K070346</u>
Device Trade Name	LabPro Data Management System v5.0	Dade Behring LabPro AlertEx Software System
General Device Characteristic Similarities		
Intended Use/Indications For Use	Microsoft Windows based software program and is intended to manage both microbial identification (ID) and antimicrobial agent susceptibility testing (AST) data generated from Beckman Coulter instruments or manually entered microbiology test results, for use by trained laboratory personnel. LabPro Alert EX is a functional subset of the LabPro Data Management System that analyzes Beckman Coulter ID and AST data, or other pre-defined parameters, against a series of established rules/ alerts and notifies the user of unusual, and/or critical	The Dade Behring LabPro AlertEx Software System is intended for use with the LabPro Data Management System Software, version 3.0 and Beckman Coulter Instruments (e.g., WalkAway SI, autoSCAN-4). The AlertEx Software notifies the user of unusual conditions, or out-of-range results that may warrant further analysis or action, and/or provides the user with the ability to change organism identifications and/or antibiotic susceptibility test interpretations.

	conditions, which may warrant further analysis or action.	
General Device Characteristic Differences		
Installed Help topics:	The new LabPro Data Management System v5.0 includes the following additional help topics: •LabPro-MBT Software Operator's Guide •LabPro software Interface Implementation Guide. •Instrument Safety Guide •WalkAway Instrument Guide •Turbidity Meter Instrument Guide •Organism Reference Guide- as an organism reference for LabPro software and Beckman Coulter instrument and panel use. •Microbiology Information Manual-supplementary information on automated identification testing. •Microbiology System Reference – includes information about Beckman Coulter Microbiology Instruments and Software.	Dade Behring Behring LabPro AlertEx Software System installed topics include: •LabPro Software Operator's Guide •LabPro Alert Ex System Guide (was part of the LabPro Software Operator's Guide).

VI Standards/Guidance Documents Referenced:

N/A

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

N/A

2. Linearity:

N/A

3. Analytical Specificity/Interference:

N/A

4. Accuracy (Instrument):

N/A

5. Carry-Over:

N/A

B Other Supportive Instrument Performance Characteristics Data:

The sponsor indicated that the proposed LabPro Data Management System software device qualifies as a Moderate Level of Concern in accordance with 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.

The documentation provided in this submission indicated that all tests were executed and completed successfully. The Pass status of each validation test workflow of the validation studies confirmed that the user needs listed in the LabPro Design Output Traceability Matrix, MB-04173 have been successfully met after introduction of the design changes outlined in the LabPro Security Design and Development Plan. The validation of the LabPro v5.0 and LabPro MBT Activation software is considered acceptable. The final build of LabPro and LabPro connect software is v5.00 Build 94; the final build of LabPro MBT Activation is v3.00 Build 3." A total of 13 tests were executed under five protocols, with 13 tests passed and none that failed. The proposed software device passed all validation testing and all acceptance criteria were met.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.