August 30, 2020

Beckman Coulter Inc.
Christina Thomas
Staff, Regulatory Affairs
1584 Enterprise Blvd
West Sacramento, California 95691

Re: K201405
Trade/Device Name: LabPro Data Management System
Regulation Number: 21 CFR 866.1645
Regulation Name: Fully Automated Short-Term Incubation Cycle Antimicrobial Susceptibility System
Regulatory Class: Class II
Product Code: LON,
Dated: May 28, 2020
Received: June 1, 2020

Dear Christina Thomas:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ribhi Shawar, Ph.D. (ABMM)
Chief
General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201405

Device Name
LabPro Data Management System

Indications for Use *(Describe)*

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 LPDMS 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

(in accordance with 21 CF 807.92)

Date: August 28, 2020

Submitter:

Beckman Coulter, Inc.
1584 Enterprise Blvd.
West Sacramento, CA 95691, USA

Contact:

Name: Christina Thomas
Title: Staff, Regulatory Affairs
Phone: 916.374.2215
Email: clthomas@beckman.com

Proposed Device Information:

Trade Name:	LabPro Data Management System
Common Name:	LabPro
510(k) Number:	K201405
Classification Regulation:	866.1645
Product Code:	LON
Device:	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation
Regulation Description:	Fully automated short-term incubation cycle antimicrobial susceptibility system
Review Panel:	Microbiology
Device Class:	2

Predicate Device Information:

Trade Name:	Dade Behring LabPro Data Management System v3.01
Common Name:	LabPro
510(k) Number:	K070346
Classification Regulation:	866.1645
Product Code:	LON
Device:	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation
Regulation Description:	Fully automated short-term incubation cycle antimicrobial susceptibility system
Review Panel:	Microbiology
Device Class:	2

Device Description

The proposed LabPro Data Management System 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 panels and select third party microbiology instruments.

The LabPro AlertEx is a functional subset of the LabPro Data Management System and analyzes Beckman Coulter ID and AST data against a series of established rules/alerts and notifies the user of unusual, and/or critical conditions.

The LabPro MBT is an optional functional subset of the LabPro Data Management System that provides connectivity to a Bruker MALDI Biotyper (MBT) System. The LabPro MBT subset software allows for transfer and display of organism identifications from the Bruker MALDI Biotyper System to the proposed LabPro Data Management System.

Indications 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 LPDMS 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.

Substantial Equivalence

The proposed LabPro Data Management System has been updated to maintain parity with currently available operating systems and databases, cybersecurity, programming languages and hardware platforms. In addition to technological advances, the proposed LabPro Data Management System offers improvements to the user experience which include consolidation of AlertEx into the LabPro Data Management System software, support of additional languages, reorganization to improve the presentation of help documentation and Alert rules, connectivity of multiple computers into a single network to improve system usability, connectivity to multiple WalkAway and autoSCAN-4 instruments to improve usability and connectivity to a Bruker MALDI Biotyper.

The differences between the proposed software and predicate device do not impact the core functionality and intended use of the LabPro Data Management System; i.e., to manage microbial identification (ID) and antimicrobial susceptibility test (AST) results from patient samples and provide the interface to ID and AST instruments attached to the system. Rather the changes enhance the overall flexibility and use of the system and provide a safe and secure software product for use in the microbiology clinical laboratory setting.

The proposed LabPro Data Management System software device and its predicate are equivalent to, or the same, with respect to mapped intended use, functionality, performance, technological characteristics as well as safety and effectiveness.

Clinical Trials

Clinical performance testing is not applicable for the proposed LabPro Data Management System, as it is a software only product.

Performance Bench Testing was performed. See Section 18 for Performance Bench Testing.

Conclusion

The proposed LabPro Data Management System was developed in accordance with 820.30 Design Controls as well as the "*FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" The software was thoroughly tested including verification and validation to ensure it will be as safe, as effective, and performed as well as the predicate device's substantially mapped functionality, when utilized within its intended use and in accordance with labeling, as demonstrated by the testing performed.

Based on the functionality and performance comparison, technological characteristic comparison and the intended use, the proposed LabPro Data Management System software device performs as intended in all aspects of the predicate devices' mapped functionality characteristics. The safety aspects of the proposed LabPro Data Management System device have been thoroughly tested in accordance with validation practices as outlined in 820.30, Design Controls. All testing passed demonstrating that the proposed LabPro Data Management System device is substantially equivalent to the predicate device in terms of intended use, functionality, performance, technological characteristics as well as safety and effectiveness.