August 15, 2025

Beckman Coulter, Inc.
Elaine Duncan
Staff Regulatory Affairs
1584 Enterprise Blvd.
West Sacramento, California 95691

Re: K250036
Trade/Device Name: MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin (DAP) (0.06-32 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: LTT, JWY, LRG, LTW
Dated: July 14, 2025
Received: July 15, 2025

Dear Elaine Duncan:

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 (the 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 available 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new

premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief, General Bacteriology and Antimicrobial Susceptibility Branch
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250036

Device Name
MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin (DAP) (0.06-32 µg/mL)

Indications for Use *(Describe)*
The MicroScan Dried Gram-Positive MIC/Combo Panel is used to determine quantitative and qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative gram-positive cocci, some fastidious aerobic gram-positive cocci and Listeria monocytogenes. After inoculation, panels are incubated for 16-20 hours at 35°C ± 1°C in a non-CO2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial daptomycin at concentrations of 0.06-32 µg/mL to the test panel. Testing is indicated for Enterococcus faecium, Enterococcus spp. other than E. faecium, and Staphylococcus spp., as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC) webpage.

The MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin (DAP) (0.06-32 µg/mL) has demonstrated acceptable performance with the following organisms:

Enterococcus faecium

Enterococcus spp. other than E. faecium (Enterococcus faecalis, Enterococcus avium, Enterococcus raffinosus, Enterococcus casseliflavus and Enterococcus durans)

Staphylococcus spp. (Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus capitis, Staphylococcus haemolyticus, Staphylococcus lugdunensis, Staphylococcus hominis, Staphylococcus warneri, Staphylococcus simulans, Staphylococcus saprophyticus, Staphylococcus intermedius, and Staphylococcus sciuri)

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.

510(k) Summary

510(k) Submission Information:

Submitter's name:	Beckman Coulter
Contact Person:	Elaine Duncan, Staff Regulatory Affairs
Address:	1584 Enterprise Blvd. West Sacramento, CA 95691
Phone:	916-318-0652
Date prepared:	August 14, 2025
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin (DAP) (0.06-32 µg/mL)
Classification:	21 CFR 866.1640 Antimicrobial Susceptibility Test Powder; Class II
Product Codes:	LTT, JWY, LRG, LTW
510(k) Notification:	Updated antimicrobial agent - Daptomycin
Predicate device:	MicroScan Dried Gram-Positive MIC/Combo Panels with Vancomycin (0.25 – 64 µg/mL) - (K150039)

510(k) Summary:

Device Description: MicroScan Dried Gram-Positive MIC/Combo Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative anaerobic gram-positive bacteria.

The principle of MicroScan panels with antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test that have been diluted in broth and dehydrated. Various antimicrobial agents are diluted in broth to concentrations bridging the range of clinical interest. Panels are rehydrated with water after inoculation with a standardized suspension of the organism. After incubation in a non-CO_2 incubator for 16-20 hours, the minimum inhibitory concentration (MIC) for the test organism is read by determining the lowest antimicrobial concentration showing inhibition of growth.

This product is single-use and intended for laboratory professional use.

Intended Use: For Use with MicroScan Dried Gram Positive MIC/Combo, Dried Gram Positive Breakpoint Combo panels. MicroScan Gram Positive panels are designed for use in determining antimicrobial agent susceptibility of rapidly growing aerobic and facultative gram-positive cocci, some fastidious aerobic gram-positive cocci and *Listeria monocytogenes*.

Indications for Use: The MicroScan Dried Gram-Positive MIC/Combo Panel is used to determine quantitative and qualitative antimicrobial agent susceptibility of colonies grown on solid media of rapidly growing aerobic and facultative gram-positive cocci, some fastidious aerobic gram-positive cocci and *Listeria monocytogenes*. After inoculation, panels are incubated for 16-20 hours at 35°C ± 1°C in a non-CO_2 incubator, and read either visually or with MicroScan instrumentation, according to the Package Insert.

This particular submission is for the addition of the antimicrobial daptomycin at concentrations of 0.06-32 µg/mL to the test panel. Testing is indicated for *Enterococcus faecium, Enterococcus* spp. other than *E. faecium,* and *Staphylococcus* spp., as recognized by the FDA Susceptibility Test Interpretive Criteria (STIC) webpage.

The MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin (DAP) (0.06 – 32 µg/mL) has demonstrated acceptable performance with the following organisms:

Enterococcus faecium

Enterococcus spp. other than E. faecium (Enterococcus faecalis, Enterococcus avium, Enterococcus raffinosus, Enterococcus casseliflavus and Enterococcus durans)

Staphylococcus spp. (Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus capitis, Staphylococcus haemolyticus, Staphylococcus lugdunensis, Staphylococcus hominis, Staphylococcus warneri, Staphylococcus simulans, Staphylococcus saprophyticus, Staphylococcus intermedius, and Staphylococcus sciuri)

Substantial Equivalence Information:

The similarities and differences of the MicroScan Dried Gram Positive MIC/Combo Panels with Daptomycin (DAP) (0.06 – 32 µg/mL) compared to the predicate device, MicroScan Dried Gram-Positive MIC/Combo Panels with Vancomycin (0.25 – 64 µg/mL) – (K150039), are described in **Table 1** below.

Table 1: Substantial Equivalence

Similarities		
Item	**Proposed** MicroScan Dried Gram-Positive MIC/Combo Panels – Daptomycin	**Predicate** MicroScan Dried Gram-Positive MIC/Combo Panels – Vancomycin (K150039)
Intended Use	Determination of susceptibility to Daptomycin with gram-positive bacteria	Determination of susceptibility to Vancomycin with gram-positive bacteria
Technology	Overnight Microdilution MIC Susceptibility Tests	Same
Specimen	Isolated colonies from cultures	Same
Incubation Temperature	35º C ± 1 º C	Same
Incubation Atmosphere	Aerobic	Same
Incubation Time	16 – 20 hours	Same
Reading Method	Automated or Manual	Same
Differences		
Item	**Proposed** MicroScan Dried Gram-Positive MIC/Combo Panels – Daptomycin	**Predicate** MicroScan Dried Gram-Negative MIC/Combo Panels – Vancomycin (K150039)
Antimicrobial Agent	Dried Daptomycin 0.06 – 32 µg/mL	Dried Vancomycin 0.25 – 64 µg/mL

Performance and Conclusion: The proposed MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin demonstrated substantially equivalent performance when compared with a CLSI frozen Reference Panel, as defined in the FDA document *Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA*, dated August 28, 2009. The Premarket Notification (510[k]) presents data in support of the MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin 0.06 – 32 µg/mL.

The external evaluations were conducted with fresh and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Gram-Positive Panel by comparing its performance with a CLSI frozen Reference panel. The Dried Gram-Positive Panel inoculated with Prompt and read on the WalkAway instrument demonstrated acceptable performance with a

Staphylococcus spp. Essential Agreement (EA) of 94.3% and Categorical Agreement (CA) of 99.5%, *Enterococcus faecium* Essential Agreement (EA) of 90.8% and Categorical Agreement (CA) of 92.0%, and *Enterococcus* species other than *E. faecium* Essential Agreement (EA) of 100.0% and Categorical Agreement (CA) of 94.1% for Daptomycin when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with Daptomycin, regardless of which inoculum method (i.e., Turbidity or Prompt), or instrument (autoSCAN-4 instrument or WalkAway system) was used.

Quality Control testing demonstrated acceptable results for Daptomycin.