November 16, 2020

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

Re: K202343
Trade/Device Name: MicroScan Dried Gram-Negative MIC/Combo Panels with Ceftazidime (Caz) (0.5-64 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY, LTT, LRG, LTW
Dated: August 13, 2020
Received: August 18, 2020

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 (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

510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Beckman Coulter
Contact name:	Elaine Duncan, Senior Analyst Regulatory Affairs
Phone:	916-374-3279
Fax:	916-374-2480
Date prepared:	August 11, 2020
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan Dried Gram-Negative MIC/Combo Panels with Ceftazidime (Caz) (0.5 - 64 µg/mL)
Intended Use:	To determine antimicrobial agent susceptibility
Classification:	Class II
Product Code:	LTT
510(k) Notification:	Updated Breakpoints – Ceftazidime
Predicate device:	MicroScan Dried Gram-Negative MIC/Combo Panels Ciprofloxacin – (K193536)

510(k) Summary:

MicroScan Dried Gram-Negative 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-negative bacilli.

The 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.

The proposed MicroScan Dried Gram-Negative MIC/Combo Panel 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-Negative MIC/Combo Panel with ceftazidime.

The external evaluations were conducted with fresh, recent and stock Efficacy isolates and stock Challenge strains. The external evaluations were designed to confirm the acceptability of the proposed Dried Gram-Negative Panel by comparing its performance with a CLSI frozen Reference panel. The Dried Gram-Negative Panel inoculated with Prompt® and read on the WalkAway instrument demonstrated acceptable performance with an *Enterobacterales* Essential Agreement (EA) of 92.1% and Categorical Agreement (CA) of 95.2%, *Pseudomonas aeruginosa* EA of 91.3% and CA of 96.2%, and *Acinetobacter* spp. EA of 93.1% and CA of 94.3% for ceftazidime when compared with the frozen Reference panel.

Inoculum and instrument reproducibility testing demonstrated acceptable reproducibility and precision with ceftazidime, 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 ceftazidime.