510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Beckman Coulter
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Date prepared:	January 22, 2019
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan Dried Gram-Negative MIC/Combo Panels with Eravacycline (ERV) (0.016-32 µg/mL)
Intended Use:	To determine antimicrobial agent susceptibility
Classification:	Class II
Product Code:	LTT
510(k) Notification:	New antimicrobial agent – Eravacycline
Predicate device:	MicroScan Dried Gram-Negative MIC/Combo Panels Ceftazidime/Avibactam – (K172337)

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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 eravacycline.

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 demonstrated acceptable performance with an overall Essential Agreement of 96.8% for eravacycline when compared with the frozen Reference panel.

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

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