SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K201423

B Applicant

Beckman Coulter, Inc.

C Proprietary and Established Names

MicroScan Dried Gram-Negative MIC/Combo Panels with Meropenem (Mer) (0.004-32 µg/mL)

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LTT, JWY, LRG, LTW	Class II	21 CFR 866.1640 - Antimicrobial Susceptibility Test Powder	MI - Microbiology

II Review Summary:

This 510(k) submission contains information/data on modifications made to the submitter's own Class II device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device.

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling.

3. A description of the device **MODIFICATION** was provided in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for the addition of *Acinetobacter* spp. as an indicated species for testing with meropenem.**

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. A Design Control Activities Summary which includes:

   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

Table 1. Performance of MicroScan Dried Gram Negative MIC/Combo Panel with Meropenem for *Acinetobacter* spp.

Inoculation Method	Reading Method	Tot	EA N	EA %	Eval Tot	Eval EA N	Eval EA %	CA Tot	CA %	No. R	No. S	min	maj	vmj
Prompt	**WalkAway**	56	51	91.1	36	31	86.1	55	98.2	37	19	1	0	0
	autoSCAN 4	56	52	92.9	37	33	89.2	55	98.2	37	19	1	0	0
	Manual	56	52	92.9	36	32	88.9	55	98.2	37	19	1	0	0
Turbidity	**WalkAway**	56	54	96.4	38	35	92.1	52	92.9	37	18	4	0	0
	autoSCAN 4	56	54	96.4	37	35	94.6	52	92.9	37	19	4	0	0
	Manual	56	54	96.4	37	35	94.6	51	91.1	37	19	5	0	0

Table 2. Observed Trending for *Acinetobacter* spp. with Meropenem

Inoculation Method	Read Method	Total Evaluable for Trending	≥ 1 Dilution lower No. (%)	Exact No. (%)	≥ 1 Dilution Higher No. (%)	Percent Difference (CI)	Trending Noted
Prompt	WalkAway	37	10 (27.0)	17 (46.0)	10 (27.0)	0	No
	autoSCAN4	40	10 (25.0)	20 (50.0)	10 (25.0)	0	No
	Manual	37	11 (29.7)	20 (54.0)	6 (16.2)	-13.5	No
Turbidity	WalkAway	42	17 (40.5)	17 (40.5)	8 (19.1)	-21.4	No
	autoSCAN4	42	19 (45.2)	16 (38.1)	7 (16.7)	-28.6	No
	Manual	41	19 (46.3)	18 (43.9)	4 (9.8)	-36.6	Yes

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.

To support the implementation of changes to FDA-recognized susceptibility test interpretive criteria (i.e., breakpoints), this submission referred to the breakpoint change protocol that was reviewed and accepted by FDA in K192355. This protocol addresses future revisions to device labeling in response to breakpoint changes that are recognized on the FDA STIC webpage (https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm410971.htm). The protocol outlined the specific procedures and acceptance criteria that Beckman Coulter intends to use to evaluate the MicroScan Dried Gram-Negative MIC/Combo Panels with Meropenem (Mer) (0.004 - 32 µg/mL) when revised breakpoints for meropenem are published on the FDA STIC webpage. The breakpoint change protocol indicated that if specific criteria are met, Beckman Coulter will update the meropenem device label to include (1) the new breakpoints, (2) an updated performance section after re-evaluation of data in this premarket notification with the new breakpoints, and (3) any new limitations as determined by their evaluation.