510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K221493

B Applicant

Beckman Coulter, Inc.

C Proprietary and Established Names

MicroScan Prompt Inoculation System-D

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LIE	Class II	21 CFR 866.1640 - Antimicrobial Susceptibility Test Powder	MI - Microbiology

II Submission/Device Overview:

A Purpose for Submission:

The purpose is to update the MicroScan Prompt Inoculation System-D device labeling. Previously obtained QC, reproducibility, and clinical data for the MicroScan Dried Gram negative and/or Gram positive MIC/Combo panels, as noted in recent 510(k) decision summaries, is applicable to support this submission.

The Prompt Inoculation method was originally developed by 3M Company and cleared in K820299 (product 6307).

B Measurand:

Standardized suspensions of bacteria equivalent to a 0.5McFrland standard.

C Type of Test:

Inoculum calibration device for microdilution Antimicrobial Susceptibility Test.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The MicroScan Prompt Inoculation System-D is used to standardize inocula for microdilution antimicrobial susceptibility tests.

The MicroScan Prompt Inoculation System-D is an accessory to the MicroScan Gram Negative and Gram Positive MIC/Combo Panels. Indications for use organisms are specific for each antimicrobial agent on the panel.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

Limitations:

1. The Prompt Inoculation System-D should not be used when the colony size is smaller than the wand tip. Examples of organisms that may not meet the size requirement are *Streptococcus* spp. other than *S. bovis* and *S. agalactiae* (Group B). Picking colonies which are too small will result in under-inoculation and may cause a resistant organism to appear to be susceptible. An alternate method of inoculum preparation should be used for colonies smaller than the wand tip.

2. Some mucoid strains of organisms such as *Klebsiella* spp. or *Pseudomonas* spp. may not adhere to the Prompt wand when attempting to pick the colony. This will be visually apparent. An alternate method of inoculum preparation should be used for such organisms.

3. Refer to the appropriate MicroScan panel Procedural Manual for each antimicrobial agent.

D Special Instrument Requirements:

Not Applicable.

IV Device/System Characteristics:

A Device Description:

The MicroScan Prompt Inoculation System-D is a method for obtaining standardized bacterial inoculum while eliminating the need for incubation and turbidity adjustment with inocula prepared according to the CLSI procedure. It consists of an inoculation wand and a bottle of diluent. The wand is a polypropylene rod with a breakaway collar that serves as a wiping mechanism. The rod is attached to a stopper. At the tip of the wand is a groove designed to hold a specific amount of bacteria equivalent to a 0.5 McFarland standard. Thirty (30) ml of diluent (Pluronic is used as the surfactant) are provided in the plastic bottle. Each kit contains 60 plastic

bottles, each containing 30 ml of stabilized aqueous Pluronic surfactants and 62 inoculation wands.

B Principle of Operation:

The MicroScan Prompt Inoculation System-D is an in vitro accessory which aids in the inoculum preparation for use with MicroSan Dried Gram positive and/or Gram negative MIC/Combo panels for quantitative and qualitative antimicrobial susceptibility testing.

The MicroScan Prompt Inoculation System-D wand is touched to several bacterial colonies on a primary isolation plate, wiped, then placed in the plastic bottle. The bacteria are suspended by shaking the bottle. The bacterial suspension, which is equivalent to a 0.5 McFarland, is stable for four hours after preparation.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Prompt Inoculation

B Predicate 510(k) Number(s):
K820299

C Comparison with Predicate(s):

Device & Predicate Device(s):	K221493 (Product No. B1026-10D)	K820299 (Product No. 6307)
Device Trade Name	MicroScan Prompt Inoculation System-D	Prompt Inoculation
General Device Characteristic Similarities		
Intended Use	Used to standardize inocula for microdilution antimicrobial susceptibility tests.	Same
Technology	At the tip of the wand is a groove designed to hold a specific amount of bacteria equivalent to a 0.5 McFarland standard.	Same
Specimen	Isolated colonies from cultures.	Same
Incubation Temperature	35°C ±1°C	Same
Incubation Atmosphere	Aerobic	Same
Incubation Time	16-20 hours (unless otherwise indicated	Same

	with an individual assay)	
General Device Characteristic Differences		
Hold Time (stability of bacteria in solution)	4 hours	2 hours
Reading Method	Automated or Manual	Manual
Antimicrobial Susceptibility Test	MicroSan MIC/Combo Panel	CLSI broth Microdilution Method
Diluents	Pluronic as the surfactant and removal of NaCL	0.02% aqueous Tween 80
Storage	2-27°C	< 27°C

VI Standards/Guidance Documents Referenced:

- Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically. 2018. Approved Standard M07-A11. Clinical and Laboratory Standards Institute, Wayne, PA.

- Guidance for Industry and FDA, Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems, August 28, 2009.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

   No new data were reviewed in this submission. Reproducibility data obtained with the Prompt Inoculation System-D was evaluated in previously conducted studies described in recent 510(k) decision summaries for the MicroScan Dried Gram negative and Gram positive MIC/Combo panels.

   In those studies, the inocula was prepared using both the turbidity and the MicroScan Prompt Inoculation System-D. Results were read manually as well as with the WalkAway and autoSCAN-4 instruments. Acceptance criteria were as noted in the Class II Special Control Guidance Document: Antimicrobial Susceptibility Test (AST) System and recent 510(k) decision summaries.

   Refer to the appropriate MicroScan Dried Gram negative and Gram positive MIC/Combo Panel Procedural Manual for each antimicrobial agent.

2. Linearity:

   Not applicable

3. Analytical Specificity/Interference:

   Not applicable

4. Assay Reportable Range:

   Not applicable

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   Inoculum Density Check:
   No new data were reviewed in this submission. Inoculum density data obtained with the Prompt Inoculation System-D were evaluated in previously conducted studies described in recent 510(k) decision summaries for the MicroScan Dried Gram negative and Gram positive MIC/Combo panels.

   Refer to the appropriate MicroScan Dried Gram-Negative and Positive MIC/Combo panels Procedural Manual and CLSI Approved Standard document M07-A11 for instructions to check inoculum densities by performing colony counts.

   Quality Control (QC):
   No new data were reviewed in this submission. QC data obtained with the Prompt Inoculation System-D were evaluated in previously conducted studies described in recent 510(k) decision summaries for the MicroScan Dried Gram negative and Gram positive MIC/Combo panels.

   Refer to appropriate MicroScan Dried Gram positive and/or Gram negative MIC/Combo panel Procedural Manual for each antimicrobial agent.

6. Detection Limit:

   Not applicable

7. Assay Cut-Off:

   Not applicable

B Comparison Studies:

1. Method Comparison with Predicate Device:

   The prompt inoculation system was developed by 3M Company and was cleared in K820299. Changes were made to the Prompt Inoculation method since the original submission in K820299 including diluents, storage temperature and the hold time (refer to comparison with the predicate device table above).

   No method comparison data were reviewed in this submission. Clinical performance data obtained with the Prompt Inoculation System-D were evaluated in previously conducted

studies described in recent 510(k) decision summaries for the MicroScan Dried Gram negative and Gram positive MIC/Combo panels for each antimicrobial agent.

Performance of the MicroScan MIC/Combo panels was evaluated using the Prompt inoculation method and the turbidity method against the CLSI broth microdilution reference method and results were analyzed based on the recommended guidelines in the AST Class II Special Controls Guidance Document issued on August 28, 2009. Any antimicrobial agent specific performance notes or limitations are included in the applicable MicroScan MIC/Combo Panel procedural manual. Refer to the appropriate MicroScan Dried Gram negative and Gram positive MIC/Combo panel Procedural Manual for each antimicrobial agent.

2. Matrix Comparison:

Not applicable

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable

2. Clinical Specificity:

Not applicable

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable

D Clinical Cut-Off:

Not applicable

E Expected Values/Reference Range:

Not applicable

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.