April 5, 2023

Beckman Coulter, Inc.
Sharon Cullen
Senior Staff Regulatory Affairs
1584 Enterprise Blvd.
West Sacramento, California 95691

Re: K221493
Trade/Device Name: MicroScan Prompt Inoculation System-D
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: LIE
Dated: May 19, 2022
Received: May 23, 2022

Dear Sharon Cullen:

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 -S

Ribhi Shawar, Ph.D. (ABMM)
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221493

Device Name
MicroScan Prompt Inoculation System-D

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Submission Information:

Device Manufacturer:	Beckman Coulter, Inc.
Address:	1584 Enterprise Blvd, West Sacramento, California 95691.
Contact name:	Sharon Cullen, Senior Staff Regulatory Affairs
Phone:	916- 844-2953
Fax:	916-374-2480
Date prepared:	March 24, 2023
Product Name:	Prompt Inoculation System - MIC
Trade Name:	MicroScan Prompt Inoculation System-D
Intended Use:	To standardize inocula for microdilution antimicrobial susceptibility tests.
Classification:	Class II
Product Code:	LIE
510(k) Notification:	K221493
Predicate device:	3M Prompt Inoculation System K820299 (product 6307)

510(k) Summary:

INTENDED 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.

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.
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Principle of Operations:

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.

Comparison with the Predicate(s):

The MicroScan Prompt Inoculation System-D is substantial equivalent to the predicate device. Refer to Substantial Equivalence Table below.

Comparison with the Predicate

Device & Predicate Device(s):	K221493 (Product No. B1026-10D)	K820299 (Product 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 with an individual assay)	Same
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

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).

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 were 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.

Inoculum Density Check. Inoculum density data is collected for the Prompt inoculum preparation for all reproducibility isolates and weekly testing of QC strain *E. coli* ATCC 25922.

The inoculum density has been evaluated in FDA's cleared 510(k) submission for the MicroScan MIC/Combo panels with each antimicrobial agent for Gram positive and Gram negative bacterial isolates.

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

Quality Control: Refer to appropriate MicroSan MIC/Combo panel Procedural Manual for each antimicrobial agent.

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.

Reproducibility:
Reproducibility 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.

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 panel Procedural Manual for each antimicrobial agent.