May 18, 2021

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

Re: K202423
Trade/Device Name: MicroScan MICroSTREP *plus* Panels with Tetracycline (0.06-16 µg/mL)
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: JWY, LTT, LRG, JTZ, LTW
Dated: August 12, 2020
Received: August 25, 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

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)*
K202423

Device Name
MicroScan MICroSTREP plus Panels with Tetracycline (0.06 – 16 µg/mL)

Indications for Use *(Describe)*
The MicroScan MICroSTREP plus Panel is used to determine quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of aerobic Streptococci and Streptococcus pneumoniae. After inoculation, panels are incubated for 20 - 24 hours at 35°C +/- 1°C in a non-CO2 incubator, and read visually according to the MicroScan Procedural Manual. Additionally, the panels may be incubated in and read by a MicroScan WalkAway instrument.

This particular Special 510(k) submission is for the addition of updated Streptococcus pneumoniae susceptibility test interpretative criteria for use with tetracycline at concentrations of 0.06 – 16 µg/mL on the MicroScan MICroSTREP plus Panel (modification to K020939 and K062923).

Tetracycline has been shown to be active in vitro against most strains of microorganisms listed below, as described in the FDA-approved package insert and/or as listed on the FDA Susceptibility Test Interpretative Criteria web site.

Streptococcus spp.
Streptococcus pneumoniae

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.

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Special 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 12, 2020
Product Name:	Microdilution Minimum Inhibitory Concentration (MIC) Panels
Trade Name:	MicroScan MICroSTREP *plus* Panels with Tetracycline (Te) (0.06 - 16 µg/mL)
Intended Use:	To determine antimicrobial agent susceptibility
Classification:	Class II
Product Codes:	LTT, LRG, JWY, JTZ
Special 510(k) Notification:	Updated FDA-recognized STIC for *Streptococcus pneumoniae* with Tetracycline
Predicate device:	MicroScan MICroSTREP *plus* Tetracycline – (K020939 and K062923)

510(k) Summary:

MicroScan MICroSTREP *plus* Panels are designed for use in determining quantitative and/or qualitative antimicrobial agent susceptibility of colonies grown on solid media of aerobic *Streptococci,* including *Streptococcus pneumoniae*. After inoculation, panels are incubated for 20 – 24 hours at 35°C±1°C in a non-CO_2 incubator, and read according to the Procedural Manual.

The antimicrobial susceptibility tests are miniaturizations of the broth dilution susceptibility test. Various antimicrobial agents are diluted in water, buffer or minute concentrations of broth to concentrations bridging the range of clinical interest. Panels are rehydrated with 115µL Mueller-Hinton broth supplemented with 2-5% lysed horse blood (LHB) and buffered with 50mM HEPES, after inoculation of the broth with a standardized suspension of the organism in saline. After incubation in a non- CO_2 incubator for 20 – 24 hours, the minimum inhibitory concentration (MIC) for the test organism is manually read by observing the lowest antimicrobial concentration showing inhibition of growth. Additionally, the panels may be incubated in and read by a MicroScan WalkAway instrument.

The proposed updated *Streptococcus pneumoniae* FDA-recognized STIC for use with the MicroScan MICroSTREP *plus* Panels with tetracycline 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. This Special Premarket Notification (510[k]) presents combined efficacy and challenge data in support of the application of updated *Streptococcus pneumoniae* STIC for use with MicroScan MICroSTREP *plus* Panels with tetracycline.

The external evaluations were conducted with fresh and stock Efficacy and Challenge isolates. The external evaluations were designed to confirm the acceptability of the updated STIC for use with the Dried MICroSTREP *plus* Panel by comparing its performance with a CLSI frozen Reference panel. The Dried MICroSTREP *plus* Panel inoculated with the turbidity inoculation method and manually read demonstrated acceptable performance with *Streptococcus pneumoniae* Essential Agreement (EA) of 90.2% and Categorical Agreement (CA) of 99.7% for tetracycline when compared with the frozen Reference panel.

Reproducibility testing located in K020939 and K062923 demonstrated acceptable reproducibility and precision with tetracycline, regardless of which read method (i.e., manual or WalkAway system) was used.

Quality Control testing demonstrated acceptable results for tetracycline.