December 28, 2017

Bio-Rad
% Fran White
President
MDC Associates, LLC
180 Cabot Street
Beverly, Massachusetts 01915

Re: K171061
Trade/Device Name: MRSASelect II
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture medium for antimicrobial susceptibility tests
Regulatory Class: Class II
Product Code: JSO
Dated: November 30, 2017
Received: December 1, 2017

Dear Fran White:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 For

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171061

Device Name
MRSASelect™II

Indications for Use *(Describe)*
MRSASelect™II is a selective and differential chromogenic medium for:

A) The qualitative detection of nasal colonization of methicillin-resistant Staphylococcus aureus (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients to screen for MRSA colonization. MRSASelect™II is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. A negative result does not preclude MRSA nasal colonization. Concomitant cultures are necessary to recover organisms for identification, antimicrobial susceptibility testing, or epidemiological typing. Results can be interpreted after 18 to 28 hours incubation.

B) The qualitative detection of methicillin-resistant Staphylococcus aureus (MRSA) from skin and soft tissue wound specimens. The MRSASelect™II is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and antimicrobial susceptibility testing are necessary for all skin and soft-tissue wound specimens. MRSASelect™II is not intended to guide, or monitor treatment for MRSA infection, or provide results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K171061
510(K) SUMMARY

Date of Summary December 12, 2017

Product Name **MRSA*Select*™II**

Sponsor
Bio-Rad Laboratories
3 Boulevard Raymond Poincaré
92430 Marnes-la-Coquette
France

Correspondent
MDC Associates, LLC
Fran White, Regulatory Consultant
180 Cabot Street
Beverly, MA 01915
Phone: (978) 927-3808
Fax: (978) 927-1308
Email: fran@mdcassoc.com

Device Identification

Trade or Proprietary Name: **MRSA*Select*™II**

Common or Usual Name: Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar

Product Code: JSO

Regulation Section: 21 CFR 866.1700

Product Classification: Class II

Intended Use

MRSA*Select™*II is a selective and differential chromogenic medium for:

A) The qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients to screen for MRSA colonization. **MRSA*Select™*II** is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. A negative result does not preclude MRSA nasal colonization. Concomitant cultures are necessary to recover organisms for identification, antimicrobial susceptibility testing, or epidemiological typing. Results can be interpreted after 18 to 28 hours incubation.

B) The qualitative detection of methicillin-resistant *Staphylococcus aureus* (MRSA) from skin and soft tissue wound specimens. The **MRSA*Select™*II** is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and antimicrobial susceptibility testing are necessary for all skin and soft-tissue wound specimens. **MRSA*Select™*II** is not intended to guide, or monitor treatment for MRSA infection, or provide results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.

K171061
510(K) SUMMARY

Device Description

MRSA*Select*™II is a selective medium for the detection and direct identification of MRSA. The selectivity of this medium is based on the presence of an antibiotic/antifungal mixture and an optimized salt concentration that inhibits the growth of yeasts and the majority of Gram negative and Gram positive bacteria, with the exception of methicillin-resistant staphylococci. Identification is based on the cleavage of a chromogenic substrate by a specific enzymatic activity of *Staphylococcus aureus*, leading to a strong pink coloration of the *Staphylococcus aureus* colonies. Plates may be read within 18-28 hours incubation:

- Methicillin-resistant *Staphylococcus aureus* produces pink colonies on **MRSA*Select*™II**;
- Coagulase negative methicillin-resistant staphylococci may not grow or may grow as colorless or white colonies;
- Methicillin-susceptible staphylococci (MSS) are inhibited.

Substantial Equivalency

The **MRSA*Select*™II** is substantially equivalent to the Bio-Rad **MRSA*Select*™** Extended Incubation (K081212) and **MRSA*Select*™** Wound Specimen (K100589) products. Table 1 on the following page compares the characteristics of the Bio-Rad **MRSA*Select*™II** (New Device) and the Bio-Rad **MRSA*Select*™** Extended Incubation (K081212) and **MRSA*Select*™** Wound Specimen (K100589) products (Predicate Devices). The differences noted do not impact the intended use and do not raise questions as the safety and effectiveness of the test (new) device.

Table 1: Comparison of New Device with Predicate Devices

SIMILARITIES			
Product Attribute	Primary Predicate Device Bio-Rad **MRSA*Select*™** Extended Incubation (K081212)	Predicate Device Bio-Rad **MRSA*Select*™** Wound Specimen (K100589)	New Device Bio-Rad **MRSA*Select*™II** Combined Nasal and Wound Culture Media Specimens
Regulation	21 CFR 866.1700	21 CFR 866.1700	21 CFR 866.1700
Product Code	JSO	JSO	JSO
Device Class	Class II	Class II	Class II
Intended Use	**MRSA*Select*™** is a selective and differential chromogenic medium for the qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients and healthcare workers to screen for MRSA colonization **MRSA*Select*™** is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. Results can be interpreted	**MRSA*Select*™** is a selective and differential chromogenic medium for the qualitative detection of methicillin-resistant *S. aureus* (MRSA) from skin and soft-tissue wound specimens. The **MRSA*Select*™** is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and susceptibility testing are necessary for all skin and soft-tissue wound specimens. **MRSA*Select*™** is	**MRSA*Select*™II** is a selective and differential chromogenic medium for: A) The qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA infections in healthcare settings. The test can be performed on anterior nares specimens from patients to screen for MRSA colonization. **MRSA*Select*™II** is not intended to diagnose MRSA infection nor to guide or monitor treatment of infection. A negative result does not preclude MRSA nasal colonization. Concomitant cultures are necessary to recover organisms for identification, antimicrobial susceptibility testing, or epidemiological typing. Results can be interpreted after 18 to 28 hours incubation. B) The qualitative detection of methicillin-

SIMILARITIES			
Product Attribute	Primary Predicate Device Bio-Rad **MRSA***Select*™ Extended Incubation (K081212)	Predicate Device Bio-Rad **MRSA***Select*™ Wound Specimen (K100589)	New Device Bio-Rad **MRSA***Select*™**II** Combined Nasal and Wound Culture Media Specimens
	after 18–28 hours incubation.	not intended nor to guide, or monitor treatment for MRSA infection, or provides results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.	resistant *Staphylococcus aureus* (MRSA) from skin and soft tissue wound specimens. The **MRSA***Select*™**II** is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA from patients with skin and soft-tissue infections. Concomitant cultures and antimicrobial susceptibility testing are necessary for all skin and soft-tissue wound specimens. **MRSA***Select*™**II** is not intended to guide, or monitor treatment for MRSA infection, or provide results of susceptibility to methicillin. Results can be interpreted after 18 to 28 hours incubation.
Product Format	Chromogenic agar	Chromogenic agar	Chromogenic agar
Read Time	18–28 hours incubation	18–28 hours incubation	18–28 hours incubation
DIFFERENCES			
Product Attribute	Primary Predicate Device Bio-Rad **MRSA***Select*™ Extended Incubation (K081212)	Predicate Device Bio-Rad **MRSA***Select*™ Wound Specimen (K100589)	New Device Bio-Rad **MRSA***Select*™**II** Combined Nasal and Wound Culture Media Specimens
Specimen Type	Anterior nares	Skin and soft-tissue wound	Anterior nares and skin and soft-tissue wound
Inoculum	Direct and Indirect (saline)	Direct	Direct

Performance Characteristics: Analytical Performance

Precision/Reproducibility

Assay precision was tested at three clinical sites and measured site-to-site reproducibility and lot-to-lot reproducibility using a blinded panel of eleven (11) organism suspensions. Ten ATCC® strains were used for the panel preparation. The panel members consisted of MRSA, MSSA and *S. epidermidis*. Results demonstrate that **MRSA***Select*™**II** is reproducible across sites and lots.

Analytical Sensitivity (Recovery Study)

The percent recovery LoD was defined as the lowest dilution at which growth is observed (> 1 CFU) on **MRSA***Select*™**II** with corresponding growth observed in parallel on Blood Agar Plate. The LoD of the **MRSA***Select*™**II** was determined using ATCC® 43300™ and NRS 660, two (2) well characterized MRSA strains from culture collections. The data confirm that the minimum concentration of MRSA reliably detected by **MRSA***Select*™**II** is 800 CFU/mL in nasal or wounds matrix.

Analytical Sensitivity (Inclusivity)

A total of 54 characterized collection strains of MRSA (including USA300-0114, USA100, 200, 300, 500, 600, 700, 800, and 1000) were inoculated onto **MRSA***Select*™**II** plates using saline suspensions at the

concentration of 80-240 CFU/mL. Isolates tested included known clinically associated strains from the Network on Antimicrobial Resistance in *Staphylococcus aureus* (NARSA) and ATCC® collections.

Table 2: Analytical Sensitivity

MRSA*Select*™II			
Reading times	***18 hours***	***24 hours***	***28 hours***
Sensitivity	53/54 (98.1%)	54/54 (100%)	54/54 (100%)

A total of 53/54 isolates grew as pink colonies at a concentration of 80-240 CFU/mL on **MRSA*Select*™II** after 18 hours. After 24 and 28 hours incubation all 54 isolates grew as pink colonies.

Analytical Specificity (Cross Reactivity)

A total of 109 strains from various species were evaluated at a minimum concentration of 10^6 CFU/mL on **MRSA*Select™*II**. Cross-reactivity was defined as growth of distinct pink colonies on **MRSA*Select™*II** at 18, 24 and 28 hours incubation. A total of 107 out of the 109 strains were inhibited or recovered as non-pink colonies on **MRSA*Select*™II**. Two strains of MSSA produced colonies with pink coloration on **MRSA*Select™*II**. An appropriate limitation has been added to the IFU. Some MRSE (Methicillin Resistant *Staphylococcus epidermidis*) strains grew as white colonies within 18-28 hours on **MRSA*Select™*II**. In addition, the following organisms grew as faint pink colonies when clustered together: *Corynebacterium imitans, Corynebacterium jeikeium, Aerococcus viridans, Staphylococcus cohnii* and *Staphylococcus sciuri*. An appropriate limitation has been added to the IFU.

Interference Study

A total of twenty (20) medicinal substances commonly used in anterior nares and on skin and soft-tissue wound specimens were evaluated for potential interference of the chromogenic reaction of the **MRSA*Select™*II**. No interference was observed with 12/20 of them. One (1) substance (Ocean Premium Saline Nasal Spray®) reduced the quantity of growth of MRSA on **MRSA*Select*™II** and BAP without complete inhibition. Seven (7) substances (Neosynephrine®, Dristan 12h®, Ayr Saline®, Walgreens First Aid Antiseptic Spray®, Tecnu First Aid Antiseptic Pain Relieving Gel, Bactine, Betadine) inhibited growth on **MRSA*Select*™II** and BAP. Appropriate limitations have been added to the IFU.

Co-Infection/Mixed Infection

The effect of mixed cultures on the performance of **MRSA*Select*™II** was assessed by inoculating MRSA in the presence of an increasing concentration of methicillin-resistant *S. epidermidis* or *K. pneumoniae*. No impact on the growth of the MRSA was observed due to co-infection.

Validation of Transport Media

The effect of three (3) different transport media on the growth of MRSA on **MRSA*Select*™II** was evaluated. The following transport media were used LQ STUART and LQ AMIES with or without charcoal. The use of these transport media did not decrease the recovery of MRSA on **MRSA*Select*™II**. An appropriate limitation has been added to the IFU.

Clinical Performance Characteristics

The performance of **MRSA*Select*™II** was evaluated at three (3) geographically diverse locations within the United States from 2013 to 2016. A total of 3,252 prospective valid wound and anterior nares specimens were included in the final data set and analyzed for product performance. All samples yielded

valid results and were included in the final analysis. Performance of **MRSA*Select*™II** was evaluated against the established reference method; for wound samples a culture enrichment broth method (Tryptic Soy Broth (TSB) with 6.5% NaCl) was used. Positive TSB cultures were subcultured on Blood Agar Plates (BAP). Identification of suspected *Staphylococcus aureus* colonies on BAP was confirmed using Gram stain, slide agglutination test for detection of *Staphylococcus aureus*, tube coagulase, and *mec*A-mediated oxacillin resistance testing using 30 µg cefoxitin disk. Similarly, for anterior nares samples, a culture enrichment broth method was used. Positive TSB cultures were subcultured on BAP. Identification of suspected *Staphylococcus aureus* colonies on BAP was confirmed followed by confirmation using Gram stain, slide agglutination test for detection of *Staphylococcus aureus***,** tube coagulase and PBP2a testing. Performance results are shown in the Table 3 and Table 4 below:

Results

Table 3: Wound Samples[c]

All Sites		**Culture Enrichment Broth (Cefoxitin)**		
		POS	NEG	TOTAL
MRSA*Select*™II (Primary Culture)	POS	147	32[a]	179
	NEG	5[b]	658	663
	TOTAL	152	690	842
All Sites			95% C.I.	
Sensitivity (%)		96.7%	96.0%	97.5%
Specificity (%)		95.4%	94.5%	96.2%
Positive Predictive Value		82.1%	80.5%	83.7%
Negative Predictive Value		99.2%	98.9%	99.6%

[a] Discordant analysis was performed for 27 of the 32 specimens identified as MRSA positive by **MRSA*Select*™II**. MRSA was confirmed in 17 of the 27 specimens using PBP2a test.
[b] Discordant analysis was performed for 5 of the 5 specimens identified as MRSA negative by **MRSA*Select*™II**. MRSA was confirmed in 3 of the 5 specimens using PBP2a test.
[c]The overall prevalence of MRSA as determined by the enriched broth culture reference method was 18% (152/842).

Table 4: Anterior Nares Samples[f]

All Sites		**Culture Enrichment Broth (PBP2a)[(c)]**		
		POS	NEG	TOTAL
MRSA*Select*™II (Primary Culture)	POS	232	37[(e)]	269
	NEG	23[(d)]	2,118	2,141
	TOTAL	255	2,155	2,410
All Sites			95% C.I.	
Sensitivity (%)		91.0%	86.8%	93.9%
Specificity (%)		98.3%	97.6%	98.8%
Pos. Predictive Value		86.2%	81.6%	89.9%
Neg. Predictive Value		98.9%	98.4%	99.3%

c) PBP2a test performed from colonies on BAP after the enrichment step in TSB (PBP2a).
No further discordant resolution was conducted on those discrepant samples.
d) All 23 specimens resulted in no growth on **MRSA*Select*™II**.
e) Of the 37 false positives observed, a total of 25 isolates were determined to be non-*S. aureus* species (including 11 strains of coagulase-negative *Staphylococcus*); and 12 isolates were identified as methicillin-susceptible *S. aureus.*
[f]The overall prevalence of MRSA as determined by the enriched broth culture reference method was 10.6% (255/2410).

Conclusions

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