DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 25, 2016

BIOMERIEUX, INC.
KAREN RUSSELL
STAFF REGULATORY AFFAIRS SPECIALIST
595 ANGLUM ROAD
HAZELWOOD MO 63042

Re: K162076
Trade/Device Name: chromID MRSA
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture medium for antimicrobial susceptibility tests
Regulatory Class: II
Product Code: JSO
Dated: July 26, 2016
Received: July 29, 2016

Dear Ms. Russell:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162076

Device Name
chromID™ MRSA agar

Indications for Use *(Describe)*
chromID™ MRSA agar 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 in healthcare settings. The test is performed on anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. chromID™ MRSA when used to detect nasal colonization is not intended to diagnose, guide, or monitor therapy for MRSA infections, or provide results of susceptibility to methicillin.

B. The qualitative detection of MRSA from skin and skin structure infections. chromID™ MRSA is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA infections. Concomitant cultures for skin and skin structure infections are necessary to recover organisms for further microbiological susceptibility testing or epidemiological typing. A negative result does not preclude MRSA infection. chromID™ MRSA is not intended to monitor treatment for MRSA infections, or provide results of susceptibility to methicillin.

C. The qualitative detection of MRSA from positive blood cultures demonstrating Gram-positive cocci on Gram stain. chromID™ MRSA is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA infections. Sub-culturing for positive blood cultures are necessary to recover organisms for further microbiological susceptibility testing or epidemiological typing. A negative result does not preclude MRSA infection. chromID™ MRSA is not intended to monitor treatment for MRSA infections, or provide results of susceptibility to methicillin.

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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chromID™ MRSA Agar:
032. 510(k) Summary

A. 510(k) Submission Information:

Submitter's Name: bioMérieux, Inc.

Address: 595 Anglum Road
Hazelwood, MO 63042

Contact Person: Karen Russell
Staff Regulatory Affairs Specialist

Phone Number: 314-731-8639
Fax Number: 314-731-8689

Date of Preparation: July 26, 2016

B. Device Name:
Formal/Trade Name: chromID™ MRSA agar

Classification Name: Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar
21 CFR 866.1700

Product Code JSO

Common Name: Culture media

C. Predicate Device: Remel Spectra MRSA (K092407)

D. 510(k) Summary:
Intended Use:

chromID™ MRSA agar 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 in healthcare settings. The test is performed on anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. chromID™ MRSA when used to detect nasal colonization is not intended to diagnose, guide, or monitor therapy for MRSA infections, or provide results of susceptibility to methicillin.

B. The qualitative detection of MRSA from skin and skin structure infections. chromID™ MRSA is indicated for use in conjunction with other laboratory tests and clinical data

available to aid in the identification and diagnosis of MRSA infections. Concomitant cultures for skin and skin structure infections are necessary to recover organisms for further microbiological susceptibility testing or epidemiological typing.

A negative result does not preclude MRSA infection. chromID™ MRSA is not intended to monitor treatment for MRSA infections, or provide results of susceptibility to methicillin.

C. The qualitative detection of MRSA from positive blood cultures demonstrating Gram-positive cocci on Gram stain.

chromID™ MRSA is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA infections. Sub-culturing for positive blood cultures are necessary to recover organisms for further microbiological susceptibility testing or epidemiological typing.

A negative result does not preclude MRSA infection. chromID™ MRSA is not intended to monitor treatment for MRSA infections, or provide results of susceptibility to methicillin.

Indications for Use:
See Intended Use Statement.

Device Description:
chromID™ MRSA agar consists of a rich nutritive base combining different peptones. It also contains a chromogenic substrate of α-glucosidase and a combination of several antibiotics, including cefoxitin, which favor the growth of MRSA including hetero-resistant strains and the direct detection of MRSA strains by revealing α-glucosidase activity (patent registered), green colonies. The selective mixture of antibiotics inhibits most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts. The MRSA strains are identified by the presence of green colonies that result from the chromogen incorporated in the medium. The chromogen targets the α-glucosidase activity of *S. aureus*. The α-glucosidase produced by *S. aureus* cleaves the chromogenic substrate, which gives a green color to the *S. aureus* colonies growing on the medium.

Substantial Equivalence
The similarities of chromID™ MRSA agar when compared to the predicate device are described in the following table.

	Device chromID™ MRSA Agar	Predicate device Remel Spectra™ MRSA (K092407)
Similarities		
Intended Use	chromID™ MRSA agar 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 in healthcare settings. The test is performed on anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. chromID™ MRSA when used to detect nasal colonization is not intended to diagnose, guide, or monitor therapy for MRSA infections, or provide results of susceptibility to methicillin. B. The qualitative detection of MRSA from skin and skin structure infections. chromID™ MRSA is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA infections. Concomitant cultures for skin and skin structure infections are necessary to recover organisms for further microbiological susceptibility testing or epidemiological typing. A negative result does not preclude MRSA infection. chromID™ MRSA is not intended to monitor treatment for MRSA infections, or provide results of susceptibility to methicillin. C. The qualitative detection of MRSA from positive blood cultures demonstrating Gram-positive cocci on Gram stain.	Remel Spectra™ MRSA is a selective and differential chromogenic medium recommended for use in the qualitative detection of nasal colonization of methicillin-resistant *Staphylococcus aureus* (MRSA) to aid in the prevention and control of MRSA in healthcare settings. The test is performed with anterior nares swab specimens from patients and healthcare workers to screen for MRSA colonization. Spectra™ MRSA is not intended to diagnose MRSA infection or to guide or monitor treatment for infections. Spectra™ MRSA is also intended for use in the qualitative detection of MRSA from positive blood cultures demonstrating Gram-positive cocci on Gram stain. Spectra™ MRSA is indicated for use in conjunction with other laboratory tests and clinical data available to the clinician as an aid in the detection of MRSA from patient positive blood cultures. Spectra™ MRSA is not intended to monitor treatment for MRSA infections, or provide results of susceptibility to methicillin. All positive blood bottles should be sub-cultured for further microbiological/ susceptibility testing.

	Device chromID™ MRSA Agar	Predicate device Remel Spectra™ MRSA (K092407)
	chromID™ MRSA is indicated for use in conjunction with other laboratory tests and clinical data available to aid in the identification and diagnosis of MRSA infections. Sub-culturing for positive blood cultures are necessary to recover organisms for further microbiological susceptibility testing or epidemiological typing. A negative result does not preclude MRSA infection. chromID™ MRSA is not intended to monitor treatment for MRSA infections, or provide results of susceptibility to methicillin.	
Test method	Manual	Manual
Specimen	Anterior nares specimens (Direct specimens) Positive blood cultures	Anterior nares specimens (Direct specimens) Positive blood cultures
Test Principle	chromID™ MRSA agar consists of a rich nutritive base combining different peptones. It also contains a chromogenic substrate of α-glucosidase and a combination of several antibiotics including cefoxitin, which favor the growth of MRSA including hetero-resistant strains and the direct detection of MRSA strains by revealing α-glucosidase activity (patient registered): green colonies. The selective mixture of antibiotics inhibits most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts. The α-glucosidase produced by *S. aureus* cleaves the chromogenic substrate, which gives a green color to the *S. aureus* colonies growing on the medium. Since the cefoxitin has inhibited non-methicillin-resistant *S. aureus* strains, only the methicillin-resistant *S. aureus* strains grow	Remel Spectra™ MRSA is an opaque medium, which uses a novel chromogen that yields a denim-blue color as a result of phosphatase activity. This enzyme is present in all *Staphylococcus aureus*, including MRSA. To allow the medium to differentiate MRSA accurately, it contains a combination of antibacterial compounds designed to inhibit the growth of a wide variety of competitor organisms. Also included are compounds that encourage the production of MRSA pathogenicity marker, ensuring expression of the phosphatase enzyme and so providing enhanced sensitivity and specificity.

	Device chromID™ MRSA Agar	Predicate device Remel Spectra™ MRSA (K092407)
	and turn green on the media.	
Differences		
Interpreting results	The α-glucosidase produced by *S. aureus* cleaves the chromogenic substrate, which produces a green color to the *S. aureus* colonies growing on the medium. Any shade of green should be interpreted as a positive result.	After 24 hours incubation, MRSA will appear as small to medium denim blue colonies against a white background. The colonies are typically smaller than on non-selective media. Other organisms (non-MRSA) will exhibit marked inhibition or produce white colonies. If after 24 hours incubation no denim blue colonies are observed, the specimen is considered negative and plates should be discarded.
Incubation Conditions	24h at 35-37°C aerobic conditions	24h at 35-37°C ambient air
Specimen	Skin and skin structure specimens	Not applicable

Both devices incorporate selective agents in the agar to inhibit most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts. Both media are selective for methicillin-resistant *Staphylococcus* and contain a chromogenic substrate that turns a specific color with growth of *Staphylococcus aureus* colonies. The differences in the two media are the selective agents and the targeted enzyme / chromogen combination resulting in the color of the *S. aureus* colonies.

Performance Characteristics

Analytical Studies

The following studies were conducted as part of K151688: Recovery (Limit of Detection), Analytical Reactivity (Challenge), Cross Reactivity (Analytical Specificity), Mixed Infection, Incubation, Expression of Resistance, and Interference Substances. These studies are also summarized below.

Reproducibility – Reproducibility of the chromID™ MRSA agar was evaluated with a set of ten well-characterized *Staphylococcus aureus* organisms, including both mecA positive and mecA negative isolates. These organisms were tested in triplicate each day at $1x10^3$ CFU/mL for five days at three clinical trial sites. Expected results were obtained 100% of the 450 times tested.

Quality Control – Two quality control organisms were tested at each study site by chromID™ MRSA on each day of testing.

Staphylococcus aureus	ATCC 29213
Staphylococcus aureus	ATCC 43300

The results for chromID™ MRSA agar QC were 100% correct for of the 297 times tested.

Recovery (Limit of Detection) - At 24 hours incubation time, the lowest concentration of MRSA organisms demonstrating growth with a positive result was 10^3 CFU/mL for one MRSA strain (ATCC® 43300) and 10^5 CFU/mL for the second MRSA strain (CDC Mu3-BR).

Analytical Reactivity (Challenge) – A challenge set composed of 80 mecA MRSA strains and 5 mecC MRSA strains was inoculated on the chromID™ MRSA agar with an inoculum equivalent to 10^3 CFU/mL. After 24 hours of incubation, 58/80 mecA MRSA strains and 4/5 mecC MRSA strains were detected on the chromID™ MRSA agar.

Cross Reactivity (Analytical Specificity) - To evaluate the analytical specificity of the chromID™ MRSA media, 71 non-MRSA strains representing bacterial and fungal species were inoculated onto chromID™ MRSA medium at a high inoculum level (10^6 CFU/mL). After 24 hours of incubation, forty-four strains did not grow and twenty strains grew colonies without green pigment. Green colonies (cross reactivity) were observed for three *Klebsiella pneumoniae* (KPC) strains, two *Staphylococcus sciuri* (oxacillin resistant) strains, one *Enterobacter cloacae* (KPC) strain, and one *Staphylococcus pseudintermedius* (oxacillin resistant) strain.

Mixed Infection - 10 MRSA strains at an organism concentration of 10^3 CFU/mL were inoculated alone and in association with 3 non-targeted strains at an organism concentration of 10^8, 10^6, or 10^4 CFU/ml. MRSA was still detected on chromID MRSA in the presence of high levels of non-target organisms.

Interfering Substances - For blood culture specimens tested in the presence of hemoglobin, triglyceride, conjugated and non-conjugated bilirubin, γ-globulin, and sodium polyanethol sulfonate, all the MRSA strains were recovered. For blood culture bottles, there was no negative effect on the growth of MRSA strains on chromID MRSA. The bottles tested in the study included BacT/ALERT® aerobic FA, FA Plus, SA and anaerobic FN, FN Plus, SN and BacTEC™ aerobic Standard, Plus, Peds Plus and anaerobic Standard, Plus and Lytic.

Incubation - The incubation times required for three MRSA strains, at an organism concentration of 10^3 CFU/mL, to produce positive chromID™ MRSA results was 20 hours for two strains and 27 hours for one strain.

Expression of Resistance - Twenty eight well-characterized *S. aureus (*10 MRSA low level methicillin-resistant, 10 high level methicillin-resistant, 5 BORSA, and 3 MSSA strains) were evaluated with chromID™ MRSA. All low level and high level methicillin-resistant strains were detected at an inoculum $\geq 10^5$ CFU/mL. At lower concentrations some strains can give colorless colonies after 24 hours of incubation.

Clinical studies

chromID™ MRSA was evaluated at four clinical sites. chromID™ MRSA performance was determined by the presence or absence of green colonies. All green colonies were tested by Gram stain, catalase and latex agglutination, and *Staphylococcus aureus* colonies were tested for resistance to oxacillin by the Cefoxitin Screen test. All green colonies were also tested for the presence of the mecA gene by PCR, and species identification was confirmed by VITEK® MS.

Positive results were defined for chromID™ MRSA as the growth of green colonies. All other results, including the growth of white colonies and no growth, were considered negative.

Every sample was also tested by the reference method, which included growth on Tryptic Soy agar with 5% sheep blood (BAP). Colonies suggestive of *Staphylococcus* species were tested by Gram stain, catalase and latex agglutination. *Staphylococcus aureus* isolates were further tested for resistance to Oxacillin by the Cefoxitin Screen test. All colonies resistant to Oxacillin by the Cefoxitin Screen test were tested for the presence of the mecA gene by PCR and by VITEK® MS for species confirmation.

Positive results for BAP were defined as growth of Cefoxitin resistant *Staphylococcus aureus* present in the media up to 48 hours. All other results, including the growth of Cefoxitin susceptible *Staphylococcus aureus*, growth of other species and no growth, were considered negative.

Blood Culture Bottle-System Type Performance Summary

Blood Culture Information	Blood Culture Bottle Type	Sensitivity n/N [%] (95% Score CI)	Specificity n/N [%] (95% Score CI)
BacT/ALERT® (vs. BAP)	FA (FAN® Aerobic)	32/32 [100.0%] (89.3 - 100%)	14/14 [100.0%] (78.5 - 100%)
	FA (FAN® Plus Aerobic)	22/22 [100.0%] (85.1 - 100%)	10/10 [100.0%] (72.3 - 100%)
	FN (FAN® Anaerobic)	31/31 [100.0%] (89.0 - 100%)	5/5 [100.0%] (56.6 - 100%)
	FN (FAN® Plus Anaerobic)	20/20 [100.0%] (83.9 - 100%)	7/7 [100.0%] (64.6 - 100%)
	SA (Standard Aerobic)	23/23 [100.0%] (85.7 - 100%)	162/164 [98.8%] (95.7 - 99.7%)
	SN (Standard Anaerobic)	25/25 [100.0%] (86.7 - 100%)	95/96 [99.0%] (94.3 – 99.8%)
	SYSTEM (Combined)	153/153 [100.0%] (97.6 - 100%)	293/296 [99.0%] (97.1 - 99.7%)
BACTEC™ (vs. BAP)	Plus Aerobic/F	30/30 [100%] (88.7 - 100%)	222/225 [98.7%] (96.2 - 99.6%)
	Lytic/10 Anaerobic/F	32/32 [100%] (89.3 - 100%)	126/127 [99.2%] (95.7 – 99.9%)
	SYSTEM (Combined)	62/62 [100.0%] (94.2 - 100%)	348/352 [98.9%] (97.1 - 99.6%)

A total of 863 positive blood culture specimens (demonstrating Gram-positive cocci) were analyzed during the clinical trial. One hundred eighty-seven cultures were removed

due to low prevalence of target (in specific blood culture bottle type) and protocol deviations.

In the clinical study, MRSA was identified in 215 positive blood cultures by the reference method and 222 positive blood cultures by chromID™ MRSA (at 24 hours). Seven discordant specimens (MRSA positive result by chromID™: MRSA negative result by reference method) were observed. Two false positives were confirmed as MRSA positive. Five false positives that grew green colonies were not identified as MRSA as per latex agglutination and Cefoxitin screen results.

chromID™ MRSA Clinical Performance Data
chromID™ MRSA (24 hours) versus BAP Reference Method (48 hours)

	Performance	2-sided 95% CI
Sensitivity	100.0% (215/215)	[98.3% – 100]%
Specificity	98.9% (641/648)	[97.8% – 99.5]%

The prevalence of MRSA detected by BAP plus confirmatory testing for MRSA was 24.9% (215/863), and the prevalence detected by chromID™ MRSA at 24 hours was 25.7% (222/863).