DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 11, 2016

BIOMERIEUX, INC.
JEWELL COULSON
SR. REGULATORY AFFAIRS SPECIALIST
595 ANGLUM RD.
HAZELWOOD MO 63042

Re: K151688
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: February 4, 2016
Received: February 8, 2016

Dear Ms. Coulson:

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)*
K151688

Device Name

chromID™ MRSA

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.

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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Section 4 : chromID™ MRSA 510(k) Summary

510(k) SUMMARY

Submitter's Name:	bioMérieux, Inc.
Address:	595 Anglum Road Hazelwood, MO 63042
Contact Person:	Jewell Coulson Senior Regulatory Affairs Specialist
Phone Number:	314 -731-7342
Fax Number:	314-731-8689
Date of Preparation:	February 4, 2016

Device :

Formal/Trade Name:	chromID™ MRSA
Common Name:	Culture media
Classification	II
Regulation Name	Culture Media for Antimicrobial Susceptibility Tests
Regulation Number	21 CFR 866.1700
Product Code	JSO

Predicate Device: Bio-Rad MRSA*Select*™ (K100589)

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.

Section 4 : chromID™ MRSA 510(k) Summary

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 (cefoxitin, etc.) that favor the growth and direct detection of MRSA, including hetero-resistant strains, by revealing α-glucosidase activity (patent registered) through the appearance of green colonies. 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. The MRSA strains are identified by the presence of green colonies that result from the chromogen incorporated in the medium. The selective mixture of antibiotics inhibits most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts.

Substantial Equivalence

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

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Section 4 : chromID™ MRSA 510(k) Summary

Item	Device chromID™ MRSA Agar	Predicate Bio-Rad MRSA*Select*™
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.	MRSA*Select*™ 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 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 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*™ 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 not intended 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.
Test method	Manual	Manual
Inoculum	Direct Specimen	Direct Specimen
Specimen	Anterior nares specimens Skin and skin structure specimens	Anterior nares specimens Skin and soft-tissue wound specimens

The chromID™ MRSA agar utilizes nutrient agar medium that contains selective and differential agents and is very similar to the MRSA*Select*™ agar. Both devices incorporate a chromogenic substrate that is enzymatically cleaved by *S. aureus* and result in colored MRSA colonies. Both devices incorporate selective agents in the agar to inhibit most bacteria not belonging to the genus *Staphylococcus*, as well as yeasts. The significant technological difference between the two media is the type of chromogenic substrate incorporated in the media to indicate the presence of MRSA colonies. The safety and effectiveness of the chromID™ MRSA agar is not impacted by the technology differences.

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Section 4 : chromID™ MRSA 510(k) Summary

Performance Characteristics:

Non-clinical (analytical) and clinical studies were performed for the chromID™ MRSA agar following the FDA Draft Guidance "Establishing the Performance Characteristics of *In Vitro* Diagnostic Devices for the Detection of Methicillin-Resistant *Staphylococcus aureus* (MRSA) for Culture Based Systems", issued June 15, 2011.

Analytical Performance

- **Reproducibility** - A set of ten mecA-positive or mecA-negative *Staphylococcus aureus* isolates were tested in triplicate each day for five days at three of the clinical study sites using multiple lots of chromID™ MRSA media. Isolates were tested at 10^3 CFU/mL and plates were read at 24 hours. The overall reproducibility rate was 100% (450/450).
- **Quality Control** - Two quality control organisms were tested at each study site by chromID™ MRSA on each day of testing. The organisms tested were:

Staphylococcus aureus	ATCC 29213
Staphylococcus aureus	ATCC 43300

The results of QC testing with chromID™ MRSA agar met the pre-defined acceptance criteria ($\geq$ 95% agreement) when compared to expected results as determined by oxacillin MIC and mecA PCR.

- **Analytical Reactivity** – A challenge set composed of 80 mecA MRSA strains and 5 mecC MRSA strains was inoculated on the chromID™ MRSA medium 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 medium.
- **Expression of Resistance** – Twenty-eight well-characterized *S. aureus* strains were tested on chromID™ MRSA (10 low level methicillin-resistant, 10 high level methicillin-resistant, 5 border-line oxacillin-resistant, and 3 methicillin-susceptible) using inoculum concentrations between 10^3 - 10^8 CFU/mL. All low level and high level methicillin-resistant strains were detected at an inoculum of $\geq 10^5$ CFU/mL. The 5 border-line oxacillin-resistant and 3 methicillin-susceptible strains did not grow, as expected, on chromID™ MRSA at inoculum concentrations as high as 10^8 CFU/mL.
- **Mixed Infection Study** – Ten MRSA strains (5 low level methicillin-resistant and 5 high level methicillin-resistant) at a concentration of 10^3 CFU/mL were inoculated on chromID™ MRSA with one of three non-MRSA strains (methicillin-susceptible *S. aureus*, methicillin-resistant coagulase negative *Staphylococcus epidermidis*, and *Escherichia coli*) at 10^4 – 10^8 CFU/mL to evaluate the recovery of MRSA on chromID™ MRSA media in the presence of non-target organisms. The presence of these non-MRSA organisms did not negatively impact chromID™ MRSA performance.
- **Recovery Study**
  Two well-characterized MRSA strains (ATCC® 43300™ and CDC Mu3-BR) were tested to determine the lowest number of CFU/mL detected on chromID™ MRSA. At 24 hours the lowest dilution for detection on chromID™ MRSA for ATCC® 43300™ was 10^3 CFU/mL and 10^5 CFU/mL for CDC Mu3-8R.
- **Cross Reactivity** - To evaluate the analytical specificity of the chromID™ MRSA media, 71 non-MRSA strains representing bacterial and fungal species potentially encountered in skin and skin structure infections were inoculated onto chromID™ MRSA medium at a high inoculum level (10^6 CFU/mL). After 24 hours of incubation, 44 strains did not grow and 20 strains grew colonies without green pigment. Green colonies (cross reactivity) were observed for 3 *Klebsiella*

pneumoniae and one *Enterobacter cloacae* strains. All 4 were carbapenemase producing (KPC). Green colonies were also observed for one *S. pseudintermedius* and 2 *S. sciuri* strains. All 3 were oxacillin-resistant strains.

- **Interference** - Interfering substances were evaluated at physiologically or biologically relevant concentrations and mixed with bacterial suspensions (9:1, v:v). No interference was observed for human blood, mucin, anticoagulants, plasma, and buffy coat. Some topical antibiotics and antiseptics interfered with MRSA detection on chromID™ MRSA due to their antibacterial activity. Use of compounds containing the active ingredients listed below may have an inhibitory effect on MRSA growth that is unrelated to chromID™ MRSA medium performance: colistimethate sodium 25 MUI/100mL, bacitracin 50,000 UI/100mL, dexamethasone 0.1g/100mL, neomycin sulfate 350,000 UI/100mL, polymixin B sulfate 600,000 UI/100mL, benzalkonium chloride 500mg/100mL, chlorhexidine digluconate 200mg/100mL, 1% hydrocortisone, 10% povidone iodine, 2% mupirocin, hydrogen peroxide 8 mg/g, ethanol 380 mg/g, 70% isopropyl alcohol. Benzocaine (14 g/L) may delay colony coloration or inhibit growth of MRSA on chromID™ MRSA.

- **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 (ATCC 43300 and *S. aureus* 0611169) and 27 hours for one strain (CDC Mu3-8R).

Clinical Studies

chromID™ MRSA was evaluated at four geographically diverse clinical sites. chromID™ MRSA performance was determined by examining the presence or absence of green colonies on the media after 24 hours. All green colonies were tested by Gram stain, catalase and latex agglutination. All *Staphylococcus aureus* colonies were tested for resistance to oxacillin by the Cefoxitin Screen test (30µg). All green colonies were also tested for the presence of the mecA gene by PCR and by VITEK® MS for species confirmation.

For the Reference Culture Method, all specimens were enriched in Tryptic Soy broth with 6.5% NaCl (TSB) for 24 hours. Negative broth cultures were incubated an additional 24 hours. Positive cultures were then subcultured to 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 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.

A positive result by Reference Culture was defined as the recovery of cefoxitin-resistant *Staphylococcus aureus* from the specimen. All other results, including the growth of cefoxitin-susceptible *Staphylococcus aureus*, growth of other species and no growth, were considered negative.

A total of 690 SSSI specimens were collected for the study at 4 external clinical laboratories. Three specimens were excluded because they did not meet specimen acceptance criteria. Seven specimens were removed due to protocol deviations. A total of 680 specimens were valid for comparison data analysis.

chromID™ MRSA at 24 Hours

Compared to Reference Culture Method (TSB) at 48 Hours

	Reference Culture Method (TSB) Result		
chromID™ MRSA Result in 24h	Pos	Neg	Total
Pos	166	13*	179
Neg	11**	490	501
Total	177	503	680

*13 discordant specimens (chromID™ MRSA result of MRSA positive; culture-based testing result of MRSA negative) were observed. 5 of the 13 chromID™ MRSA positive specimens were confirmed as MRSA by Cefoxitin Screen Test. 8 cultures grew green colonies on chromID™ MRSA that were not MRSA.

**11 discordant specimens (chromID™ MRSA result of MRSA negative: culture-based testing result of MRSA positive) were observed. 6 cultures displayed no growth on chromID™ MRSA. 4 cultures grew non-green MRSA colonies on chromID™ MRSA. One specimen grew green colonies on chromID™ MRSA that were not identified as MRSA.

Specificity 97.4% (95% CI: [95.6-98.5])
Sensitivity 93.8% (95% CI: [89.2-96.5])

The overall prevalence of MRSA in this study by the Reference Culture Method was 26.0% (177/680). . The prevalence of MRSA as determined by chromID™ MRSA at 24 hours was 26.3% (179/680).

Conclusion
A comparison of the intended use and the results of non-clinical and clinical performance studies support that chromID™ MRSA agar is substantially equivalent to the predicate device.