DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 27, 2017

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

Re: K163042
Trade/Device Name: ChromID® Strepto B Agar
Regulation Number: 21 CFR 866.2360
Regulation Name: Selective culture medium
Regulatory Class: I
Product Code: PQZ
Dated: October 28, 2016
Received: October 31, 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 -A

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)*
K163042

Device Name
chromID® Strepto B agar

Indications for Use *(Describe)*
chromID® Strepto B agar is a selective chromogenic medium that is intended to aid in the qualitative determination of Group B Streptococcus (GBS) colonization in pregnant women. This medium supports the growth of, but does not differentiate between, hemolytic and non-hemolytic GBS strains. The test is performed on 18-24 hour LIM broth enrichments of vaginal/rectal swabs obtained from pregnant women. chromID® Strepto B agar results can be interpreted after 24 hours incubation with confirmation of characteristic GBS colonies from the media.

chromID® Strepto B agar is not intended to diagnose infection nor to guide or monitor treatment for infections. chromID® Strepto B agar does not provide susceptibility results. Subculture to non-selective media should be performed as needed for susceptibility testing. chromID® Strepto B agar is intended for use by laboratory health practitioners in a clinical laboratory.

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 030. 510(k) SUMMARY

510(k) SUMMARY
chromID® Strepto B agar

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: October 28, 2016

B. Device Name:

Formal/Trade Name: chromID® Strepto B agar

Classification Name: 21 CFR 866.2360
Selective culture medium

Product Code PQZ

Common Name: Selective Culture Media

C. Predicate Device: Modified Selective Streptococcus Agar (K881577)

D. 510(k) Summary:

Intended Use:

chromID® Strepto B agar is a selective chromogenic medium that is intended to aid in the qualitative determination of Group B Streptococcus (GBS) colonization in pregnant women. This medium supports the growth of, but does not differentiate between, hemolytic and non-hemolytic GBS strains. The test is performed on 18-24 hour LIM broth enrichments of vaginal/rectal swabs obtained from pregnant women. chromID® Strepto B agar results can be interpreted after 24 hours incubation with confirmation of characteristic GBS colonies from the media.

chromID® Strepto B agar is not intended to diagnose infection nor to guide or monitor treatment for infections. chromID® Strepto B agar does not provide susceptibility results. Subculture to non-selective media should be performed as needed for susceptibility testing. chromID® Strepto B agar is intended for use by laboratory health practitioners in a clinical laboratory.

Indications for use:
See Intended use

Device Description:
chromID Strepto B agar consists of a nutritive base combining different peptones, chromogenic substrates and antibiotics. These components enable the screening of *S. agalactiae* by the spontaneous appearance of pale pink to red colonies. Most other bacterial species and yeasts do not grow on this medium or do not produce typical colonies.

Substantial Equivalence:
The similarities and differences between chromID® Strepto B agar and the predicate device are described in the following table:

Category	**Predicate Device** **Acumedia Manufacturers, Inc.** **Modified Selective Streptococcus Agar** **K881577**	**Device** **bioMérieux, Inc.** **chromID® Strepto B agar** **K163042**
Classification, and Product code	Class 1 21 CFR 866.2360 JSI	Class 1 21 CFR 866.2360 PQZ
Intended Use	Selective agar medium for the isolation and detection of pathogenic Streptococci.	chromID® Strepto B agar is a selective chromogenic medium that is intended to aid in the qualitative determination of Group B Streptococcus (GBS) colonization in pregnant women. This medium supports the growth of, but does not differentiate between, hemolytic and non-hemolytic GBS strains. The test is performed on 18-24 hour LIM broth enrichments of vaginal/rectal swabs obtained from pregnant women. chromID® Strepto B agar results can be interpreted after 24 hours incubation with confirmation of characteristic GBS colonies from the media. chromID® Strepto B agar is not intended to diagnose infection nor to guide or monitor treatment for infections. chromID® Strepto B agar does not provide susceptibility results. Subculture to non-selective media should be performed as needed for susceptibility testing. chromID® Strepto B agar is intended for use by laboratory health practitioners in a clinical laboratory.

Category	Predicate Device Acumedia Manufacturers, Inc. Modified Selective Streptococcus Agar K881577	Device bioMérieux, Inc. chromID® Strepto B agar K163042
Test method	Manual, culture media	Manual, culture media
Sample Types	Direct from Specimen	Vaginal/rectal swab enriched in Lim broth
Interpretation of positive results	For the detection of Streptococci, examine medium for growth and hemolytic reactions (e.g. alpha-hemolysis, beta-hemolysis, or no hemolysis) after 18 - 24 and 48 hours incubation.	For the detection of GBS, observe bacterial growth and the appearance of colonies. Typical GBS colonies are pale pink to red.
Quality Control	Incubate at 35 ± 2°C. Examine for growth after 18 - 24 hours.	Incubate in the dark at 35-37°C. Examine for growth after 24 hours. QC strains: *Streptococcus agalactiae* ATCC 12386 (positive control) and *Staphylococcus aureus* ATCC 6538 (negative control)
Storage	2 - 30°C.	2 - 8°C

Both the devices use a selective media for the detection of Streptococci. Their formulas and method of inoculation are similar. The differences between chromID® Strepto B agar and the predicate device are related to the storage temperature, QC method, and interpretation of results.

Performance Characteristics:

Analytical Studies

The following analytical studies were conducted to evaluate the performance of chromID® Strepto B medium: Analytical Reactivity (Challenge), Analytical Specificity (Cross Reactivity), Incubation Time, Interference, Recovery, and Mixed Infection. All analytical performance studies demonstrated acceptable results.

Recovery Study-Two well-characterized GBS strains (ATCC 12386, hemolytic and ATCC 13813, non-hemolytic) were tested to determine the lowest CFU/ml detected on chromID Strepto B medium. For both strains, the last dilution for which visible growth with characteristic colonies was observed was 10^3 CFU/ml.

Analytical Reactivity (Challenge)-A challenge set of 20 GBS strains (hemolytic and non-hemolytic) was inoculated on the chromID Strepto B medium at low inoculum (10^3 CFU/ml). After 18, 24 and 48 hours, 12/20, 17/20 and 20/20 strains were detected on the chromID® Strepto B medium, respectively.

Analytical Specificity (Cross Reactivity)-To evaluate the analytical specificity of the chromID StreptoB medium with non-GBS organisms, 88 strains representing bacterial and fungal species potentially encountered in vaginal/rectal samples were inoculated onto chromID® Strepto B medium at high inoculum (10^6 CFU/ml). After 24 hours of incubation, 20/88 strains grew on the medium with 3 strains producing characteristic colonies (Streptococcus Group C, *Streptococcus mitis*, and *Klebsiella pneumoniae* (KPC)). After 48 hours, 30/88 grew on the medium and 6 strains producing characteristic colonies (Streptococcus Group C, *Streptococcus mitis*, *Streptococcus pyogenes*, *Streptococcus anginosus*, *Staphylococcus aureus* (MRSA), *Lactobacillus sakei*).

Mixed Infection-This study was conducted to evaluate the performance of chromID Strepto B agar in recovering GBS in the presence of high levels of non-target organisms. Seven non-target organisms were tested in the study that included strains known to produce pale pink to red colonies on chromID® Strepto B medium from the Cross Reactivity Study. For those non-target strains yielding pink to red colonies on chromID® Strepto B medium, colony features were used to distinguish GBS from non-target organisms. Two GBS strains (one hemolytic and one non-hemolytic) were incubated at approximately 10^3 CFU/ml with each non-target organism. At 24 hrs, both GBS strains were detected in the presence of 10^8 CFU/ml of non-target organism, except in the presence of Streptococcus Group C (NCTC 8546). At this concentration (10^8 CFU/ml), 5/7 non-target organisms gave characteristic colonies when grown on chromID® Strepto B medium. The 2 GBS strains gave characteristic colonies as expected when tested in the presence of non-target organisms diluted below 10^8 CFU/ml (10^3-10^7 CFU/ml) at 24 hrs. It was noted that all non-target organisms incubated with GBS either did not grow or grew as non-characteristic colonies on chromID Strepto B agar when diluted from 10^3-10^5 CFU/ml.

Incubation Ten (10) GBS strains (hemolytic and non-hemolytic) were inoculated on the chromID® Strepto B medium at low inoculum (10^3 CFU/ml). The growth and the presence of characteristic colonies were evaluated every hour across a range that represented different target times: 18 hrs (16-20 hrs), 24 hrs (21-28 hrs), and 48 hrs (44-52 hrs). The number of strains showing characteristic colonies ranged between 5/10 (at 16 and 17 hours) and 10/10 from 44 hours and after. At 24 hours, 8/10 GBS strains showed characteristic colonies.

Interfering Substances No interference was observed for vaginal fluid, amniotic fluid, sperm, whole blood, concentrated buffy coat and stool. Of the 15 interfering substances tested, two (naproxen sodium and topical agent) demonstrated partial inhibition of GBS growth on chromID StreptoB medium. Use of compounds containing the active ingredients below had an inhibitory effect on GBS growth that was unrelated to chromID StreptoB medium performance: nystatin (10^4 UI/ml), hydrocortisone (0.625 mg/ml), aluminum hydroxide (2.125 mg/ml)/magnesium hydroxide (2.250 mg/ml), mesalazine (5 mg/ml), barium sulfate (5 mg/ml), esomeprazole (1 mg/ml), loperamide (1 mg/ml), sennosides (40 mg/ml), metronidazole (25 mg/ml), lidocaine (2.5 mg/ml), econazole (7.2 mg/ml), naproxen sodium (27.5 mg/ml), nonoxynol-9 (one condom/50 ml sterile water; used at 1:1 dilution), benzalkonium chloride (1 wipe/100 ml sterile water; used at 1:1 dilution).

Clinical Studies

Reproducibility and QC

Reproducibility and Quality Control were performed during the clinical studies.
Quality Control and Reproducibility strains were subcultured to BAP each day of testing and observed for growth to ensure purity and the viability of the organism.

Reproducibility of the chromID® Strepto B agar was evaluated with 11 organisms including one non-hemolytic strain of *Streptococcus agalactiae,* and one *Staphylococcus aureus* strain. These organisms were tested at three of the trial sites. Expected results were obtained 100% of the 990 times tested.

Quality Control was performed with two quality control organisms tested at each study site by chromID Strepto B agar on each day of comparative and reproducibility testing:

Streptococcus agalactiae ATCC 12386, positive control

Staphylococcus aureus ATCC 6538 negative control

The results for chromID Strepto B agar were 100% correct for the 107 times tested.

Prospective Clinical Study

Clinical studies were conducted at three external sites with fresh clinical specimens. These studies were designed to evaluate the recovery *Streptococcus agalactiae* from 18-24 hour LIM broth enrichments of vaginal/rectal swab specimens (from pregnant women) by chromID Strepto B agar. Positive results were defined for chromID Strepto B agar as the growth of pale pink to red colonies. No growth or colonies presenting as other than pale pink to red in appearance were interpreted as a negative result. All colony types growing on chromID Strepto B agar were characterized using one or more of the following laboratory tests: gram stain, catalase, PYR testing, and latex agglutination. In addition, VITEK® MS was used to identify all organisms growing on chromID® Strepto B agar. For the Reference Culture Method, turbid LIM broth cultures were subcultured to CNA agar, and all suspicious colonies were screened to confirm or rule-out the presence of GBS using established laboratory methods: gram stain, catalase, PYR testing, and latex agglutination. VITEK MS was also used to confirm the identification of GBS by the Reference Method. Negative broth enriched specimens were incubated an additional 24 hours before calling samples negative by the Reference Culture Method.

A total of 681 vaginal/rectal specimens enriched in LIM broth per CDC guidelines were analyzed during the clinical trial. There were 60 isolates and 5 cultures removed due to protocol deviations.

There were 172 cultures that were positive for Group B *Streptococcus* (GBS) by chromID Strepto B (24 hours) and by the Reference Culture Method.

chromID 24hr vs. Reference Culture Method

	Number	Ntotal	Performance	2-sided 95% Score CI
Sensitivity	172	176	97.7%	[94.3 - 99.1]%
Specificity	465	505	92.1%	[89.4 - 94.1]%

Comparison of chromID® Strepto B at 24 hours to the Reference Culture Method resulted in a Sensitivity of 97.7% (95% CI: 94.3% - 99.1%) and Specificity of 92.1% (95% CI: 89.4 % - 94.1%)

At 24 hours, a total of 212 cultures were positive by chromID Strepto B and 176 were positive by the Reference Method. Of the 40 false positive cultures, four cultures that were positive for GBS by chromID Strepto B agar were confirmed as GBS positive by characteristic color, Gram staining, catalase reaction, Lancefield Group B positive latex agglutination, and VITEK® MS identification. The remaining 36 false positives demonstrated pale pink to red colored colonies that were not confirmed as GBS.

In the chromID Strepto B clinical study, the prevalence of GBS detected by the Reference Culture Method was 25.8% (176/681).

The chromID Strepto B medium is a screening agar medium based on colony coloration, thus it further requires identification of pale pink to red *Streptococcus agalactiae* colonies using a laboratory approved procedure. The medium also has the ability to recover both hemolytic and non-hemolytic strains of *Streptococcus agalactiae*. The clinical trial has shown chromID Strepto B agar to be a safe and effective when used in the clinical setting.

Conclusion

The analytical and clinical data demonstrate that chromID® Strepto B medium is substantially equivalent to the predicate device.