K070691

## 510(k) SUMMARY

**SUBMITTED BY:** BECTON, DICKINSON AND COMPANY
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**CONTACT NAME:** Dennis Mertz, Sr. Manager, Regulatory Affairs

NOV 20 2007

**DATE PREPARED:** November 8, 2007

**DEVICE TRADE NAME:** BBL™ CHROMagar™ O157

**DEVICE COMMON NAME:** Differential Culture Medium

**DEVICE CLASSIFICATION:** 21 CFR § 866.2360 Class I

**PREDICATE DEVICES:** BBL™ MacConkey II Agar with Sorbitol (K871855)

**INTENDED USE:**

BBL™ CHROMagar™ O157 is a selective medium for the isolation, differentiation and presumptive identification of *Escherichia coli* O157:H7 from clinical human stool specimens.

**DEVICE DESCRIPTION:**

BBL™ CHROMagar™ O157 formulation incorporates chromogenic substrates, which allow colonies of *E. coli* O157:H7 to produce a mauve color for presumptive identification from the primary isolation plate and differentiation from other organisms. Specially selected Difco™ peptones are incorporated to supply nutrients. The addition of potassium tellurite, cefixime and cefsulodin reduces the number of bacteria other than *E. coli* O157:H7 that grow on this medium. The chromogen mix consists of artificial substrates (chromogens), which release an insoluble colored compound when hydrolyzed by a specific enzyme. *E. coli* O157:H7 utilizes one of the chromogenic substrates producing mauve colonies. The growth of mauve colonies is considered presumptive for *E. coli* O157:H7 on BBL™ CHROMagar™ O157. Non-*E. coli* O157:H7 bacteria may utilize other chromogenic substrates resulting in blue to blue-green colored colonies or, if none of the chromogenic substrates are utilized, colonies may appear as their natural color. These visually distinct colored colonies facilitate the detection and differentiation of *E. coli* O157:H7 from other organisms.

**DEVICE COMPARISON:**

The BBL™ CHROMagar™ O157 medium differs from the BBL™ MacConkey II Agar with Sorbitol medium in the following ways:

- BBL CHROMagar O157 utilizes a chromogenic mix to differentiate *E. coli* O157:H7 from other *E. coli* and fecal organisms, whereas BBL MacConkey II Agar with Sorbitol utilizes sorbitol and neutral red indicator to differentiate *E. coli* O157:H7 from other *E. coli* strains.
- BBL CHROMagar O157 utilizes tellurite, cefixime and cefsulodin as selective agents to reduce and/or inhibit bacterial growth other than *E. coli* O157:H7, whereas BBL MacConkey II Agar with Sorbitol utilizes bile salts and crystal violet as selective agents to reduce and/or inhibit bacterial growth.
- BBL CHROMagar O157 presumptively identifies *E. coli* O157:H7 by its ability to hydrolyze a specific substrate that produces a mauve color, whereas BBL MacConkey II Agar with Sorbitol presumptively identifies *E. coli* O157:H7 by its inability to ferment sorbitol thereby producing a colorless colony.

Although there are some differences between the BBL™ CHROMagar™ O157 device and its predicate device (BBL™ MacConkey II Agar with Sorbitol), these differences do not present new issues of safety and effectiveness. The impact of these differences on the safety and effectiveness of the BBL™ CHROMagar™ O157 device can be assessed by using accepted scientific methods. Comparative performance data are presented in this submission.

The following table shows the comparison of device characteristics of BBL CHROMagar O157 to BBL MacConkey II Agar with Sorbitol.

**Table 1: Device Characteristics Comparison of BBL CHROMagar O157 to BBL MacConkey II Agar with Sorbitol (SMAC)**

| Device Characteristic | BBL CHROMagar O157 | BBL MacConkey II Agar with Sorbitol (SMAC) (K871855) |
|---|---|---|
| Intended Use | BBL CHROMagar O157 is a selective medium for the isolation, differential and presumptive identification of *Escherichia coli* O157:H7 from clinical stool sources. | BBL MacConkey II Agar with Sorbitol is used as a selective and differential medium for the detection of *Escherichia coli* serotype O157:H7 associated with hemorrhagic colitis. |
| Specimen type | Clinical specimens | Clinical specimens |
| Inoculation | Direct from specimen or specimen collection device. | Direct from specimen or specimen collection device |
| Storage Conditions | Refrigeration at 2 – 8°C away from light | Refrigeration at 2 – 8°C |
| Incubation Temperature | Incubation at 35 ± 2°C, protected from light | Incubation at 35 ± 2°C, protected from light |
| Incubation Length | 18-24 h. | 18-24 h. |
| Selective Inhibitory agents | Tellurite, Cefixime, and Cefsulodin | Bile salt and Crystal Violet |
| Testing Method | Manual | Manual |
| Growth Detection | Identification at 18-24 h. | Identification at 18-24 h. |
| Organism Differentiation | Chromogen mix substrates facilitate visual differentiation of *E. coli* O157:H7 from other *E. coli* and other fecal organisms. | Sorbitol and Neutral red indicator facilitate visual differentiation of *E. coli* O157:H7 from other *E. coli* and other fecal organisms. |
| Shelf Life | 12 weeks | 12 weeks |

**SUMMARY OF PERFORMANCE DATA:**

**ANALYTICAL STUDIES:**

**Internal Studies:**

An internal evaluation of BBL™ CHROMagar™ O157 was performed in the Research & Development Laboratory of BD Diagnostic Systems. Testing included 1) a study comparing the performance of BBL™ CHROMagar™ O157 to two commercially available, selective and differential media used for the presumptive identification for *E. coli* O157:H7 [BBL™ MacConkey II Agar with Sorbitol (SMAC) and BBL™ Sorbitol MacConkey II Agar with Cefixime and Tellurite (SMAC-CT)], 2) a Limit of Detection study, and 3) a verification study of product performance using a latex agglutination test. These tests demonstrate that BBL CHROMagar O157 performs as well as the predicate device, SMAC and another commercially available medium (SMAC-CT) in presumptively identifying *E. coli O157:H7.*

Additional analytical studies were conducted with BBL CHROMagar O157 to demonstrate the performance of the medium under a number of variable conditions. This testing included 1) a cross reactivity study using fifty-nine (59) non-*E. coli* O157:H7 organisms including various species from the following Geneses: Salmonella, Shigella, Yersinia, Vibrio, Aeromonas, Campylobacter and Plesiomonas, and 2) an interference study using fourteen (14) substances that may be present in stool or rectal specimens. These substances included lubricants, water, soap, laxatives, suppositories and various hemorrhoidal treatments.

The results for the cross reactivity study indicated that only one of the 59 organisms, Salmonella serotype Heidelberg, exhibited mauve colonies when plated on BBL CHROMagar O157. The results of the interference study showed that none of the substances tested interfered with the performance of the BBL CHROMagar O157 medium.

**External Studies:**

A clinical study was conducted at an external centralized regional clinical laboratory that rountinely tests for E. coli O157:H7 in stool specimens. Stoll specimens were inoculated onto Sorital-MacConkey (SMAC) and BBL CHROMagar O157 media and incubated aerobically for 18-24 hours at 35°C. Each Plate was read by an independent technologist and confirmatory testing (indole and serotyping) was conducted on all suspected colony samples. A total of 3,136 stool specimens were cultured, of which 2,855 specimens provided acceptable results for this study while 281 specimens were determined to be noncompliant to the required testing matrix. The following table shows the breakdown of the results from this study:

| | SMAC Result | |
|---|---|---|
| CHROMagar Result | Positive | Negative |
| Positive | 19 | 5 |
| Negative | 3 | 2828 |
| Totals | 22 | 2833 |

Positive Percent Agreement: 86.4%

Negative Percent Agreement: 99.8%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
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NOV 2 0 2007

Mr. Dennis Mertz
Senior Manager, Regulatory Affairs
Becton, Dickinson and Company
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Sparks, MD 21152

Re: k070691
Trade/Device Name: BBL™ CHROMagar ™ O157
Regulation Number: 21 CFR 866.2360
Regulation Name: Differential Culture Medium
Regulatory Class: Class I
Product Code: JSI
Dated: October 10 2007
Received: October 11, 2007

Dear Mr. Mertz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

510(k) Number: K070691

Device Name: BD BBL™ CHROMagar™ O157

Indication For Use:

BD BBL™ CHROMagar™ O157 is a selective medium for the isolation, differentiation and presumptive identification of *Escherichia coli* O157:H7 from clinical human stool specimens.

Prescription Use X And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070691