DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 1, 2017

REMEL, INC.
CYNTHIA KNAPP
DIRECTOR R&D, AST AND PHARMA, MICROBIOLOGY
12076 SANTA FE DRIVE
LENEXA KS 66215

Re: K162620
Trade/Device Name: Remel Spectra ESBL
Regulation Number: 21 CFR 866.1700
Regulation Name: Culture medium for antimicrobial susceptibility tests
Regulatory Class: II
Product Code: JSO
Dated: March 29, 2017
Received: March 30, 2017

Dear Ms. Knapp:

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)*
K162620

Device Name
Remel Spectra ESBL

Indications for Use *(Describe)*

Remel Spectra ESBL is a selective and differential growth medium for use in primary isolation and presumptive identification of Extended Spectrum β Lactamase (ESBL)-producing *Escherichia coli*, *Klebsiella pneumoniae*, *Klebsiella oxytoca* and *Proteus mirabilis* to aid in prevention and control of these bacteria in a healthcare setting. Testing may be performed from either perirectal swabs or fresh stool specimens. Remel Spectra ESBL is not intended to diagnose ESBL infection, or to guide or monitor treatment.

Do not report Spectra ESBL positive screening results. Subculture of presumptively positive colonies to non-selective medium (e.g., Tryptic Soy Agar with 5% sheep blood) is required for organism identification, confirmatory testing for ESBL, susceptibility testing and epidemiological typing.

A lack of growth or the absence of pink, blue-turquoise-green or tan colonies on Spectra ESBL does not preclude the presence of ESBL producing organisms.

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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510(k) Summary

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Date Prepared: April 28, 2017

Proprietary Name: Remel Spectra™ ESBL

Common Name: Chromogenic ESBL

Device Classification: 21 CFR 866.1700: Culture medium for antimicrobial susceptibility tests.

Intended Use: Remel Spectra™ ESBL is a selective and differential growth medium for use in primary isolation and presumptive identification of Extended Spectrum β Lactamase (ESBL)-producing *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca* and *Proteus mirabilis* to aid in prevention and control of these bacteria in a healthcare setting. Testing may be performed from either perirectal swabs or fresh stool specimens. Remel Spectra™ ESBL is not intended to diagnose ESBL infection, or to guide or monitor treatment.

Do not report Spectra™ ESBL positive screening results. Subculture of presumptive positive colonies to non-selective medium (e.g. Tryptic Soy Agar with 5% sheep blood) is required for organism identification, confirmatory testing for ESBL, susceptibility testing and epidemiological typing.

A lack of growth or the absence of pink, blue-turquoise-green or tan colonies on Spectra™ ESBL does not preclude the presence of ESBL producing organisms.

Device Description Spectra™ ESBL contains a combination of antibacterial agents which aid in inhibiting non-ESBL Enterobacteriaceae and suppress the growth of some AmpC organisms and other non-ESBL flora. Peptones supply amino acids and essential nutrients which promote the growth of enteric gram-negative bacilli. Sodium chloride is a source of essential

electrolytes and maintains osmotic equilibrium. Phosphate buffers are added to maintain the pH.

A mixture of chromogens forms a substrate for two enzymes: β-galactosidase and glucuronidase that are differentially expressed in different species of bacteria resulting in blue/turquoise-green or pink colonies. Other ESBL-producing organisms that do not utilize the chromogenic substrates may produce tan colonies through deamination of tryptophan. Non-target organisms generally appear cream colored or are naturally pigmented green or brown.

Formulation:

REAGENTS (CLASSICAL FORMULA)*

Peptone Mix	12.0	g
Sodium Chloride	5.0	g
Phosphate Buffers	4.0	g
Chromogenic Mix	4.0	g
Antibiotic Mix	0.28	g
Agar	15.0	g
Demineralized Water	1000.0	ml

pH 6.9 ± 0.2 @ 25°C

*Adjusted as required to meet performance standards.

Device Comparison:

Substantial Equivalence Information:

Predicate K number: K160512, HardyCHROM™ ESBL

Characteristic	Remel Spectra™ ESBL	HardyCHROM™ ESBL
Similarities		
Regulation	21 CFR 866.1700	Same
Product Code	JSO	Same
Device Class	II	Same
Intended Use	Remel Spectra™ ESBL is a selective and differential growth medium for use in primary isolation and presumptive identification of	HardyCHROM™ ESBL is a selective and differential chromogenic medium which is intended for the qualitative and presumptive

	Extended Spectrum B Lactamase (ESBL)- producing *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca* and *Proteus mirabilis* to aid in prevention and control of these bacteria in a healthcare setting. Testing may be performed from either perirectal swabs or fresh stool specimens. Remel Spectra™ ESBL is not intended to diagnose ESBL infection, or to guide or monitor treatment. Do not report Spectra™ ESBL positive screening results. Subculture of presumptively positive colonies to non-selective medium (e.g. Tryptic Soy Agar with 5% sheep blood) is required for organism identification, confirmatory testing for ESBL, susceptibility testing and epidemiological typing. A lack of growth or the absence of pink, blue-turquoise-green or tan colonies on Spectra™ ESBL does not preclude the presence of ESBL producing organisms.	detection from stool specimens of: 1) *Enterobacteriaceae* that are potentially non-susceptible to ceftazidime and cefpodoxime; and 2) Extended-spectrum beta-lactamase (ESBL)-producing *Escherichia coli*, *Klebsiella pneumoniae* and *Klebsiella oxytoca.* The test is performed on stool specimens from patients at risk of harboring *Enterobacteriaceae* that are non-susceptible to 3rd generation cephalosporins or ESBL-producing *E. coli*, *K. pneumoniae* and *K. oxytoca*, and is intended as an aid in the detection, identification of colonization and control of these bacteria in a healthcare setting. HardyCHROM™ ESBL is not intended to diagnose infection or to guide or monitor treatment for infections. Results can be interpreted after incubation for 18-24 hours. Subculture to non-selective medium is required for confirming identification, antimicrobial susceptibility testing and epidemiological typing. A lack of growth or the absence of pink, blue or yellow/gold colonies on HardyCHROM™ ESBL does not preclude the presence of *Enterobacteriaceae* that are non-susceptible to 3rd generation cephalosporins or ESBL producing organisms.
Inoculation	Direct Specimen	Same
Specimen Type	Clinical Fecal Specimens and Perirectal Swabs	Clinical Fecal Specimens
Test Methodology	Manual	Same
Storage Conditions	Refrigeration at 2-8°C	Same

Incubation Temperature	Incubation at 35+/-2°C	Same
Interpretation of Results	Manual, visual	Same
Shelf Life	12 weeks	Same
Incubation Length	18-24 hours	Same
Organisms Detected	ESBL producing strains of *E. coli, K. pneumoniae, K. oxytoca* and *P. mirabilis*	ESBL-producing strains of *E. coli, K. pneumoniae,* and *K. oxytoca* 3rd generation cephalosporin non-susceptible *Enterobacteriaceae*

Summary of Performance Testing - Clinical

The performance of Remel Spectra™ ESBL was evaluated at three different clinical hospitals in the United States. A total of 1176 prospective rectal swab (439) and fecal (737) surveillance specimens were evaluated. Results from Spectra™ ESBL at 18-24 hours incubation were compared to those obtained from growth on MacConkey agar with a 10µg cefpodoxime disk between the 1st and 2nd quadrants and selection of colonies from within the zone of inhibition, followed by biochemical identification and disk diffusion phenotypic confirmatory antimicrobial susceptibility testing for ESBLs as outlined in the Clinical and Laboratory Standards Institute document M100-S23.

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Table 1. Gender and Demographic Summary of Subjects in Spectra™ ESBL Clinical Study

Gender	Location			Total
	Site 1	Site 2	Site 3	
Female	206	183	159	548
Male	232	226	167	625
Unknown	0	0	3	3
Total	**438**[1]	**409**[2]	**329**[2]	**1176**

[1] All perirectal swabs
[2] 408/409 fresh stool 1/409 perirectal swab
[3] All fresh stool

Table 2. Age and Demographic Summary of Subjects in Spectra™ ESBL Clinical Study

Age Range	Location			
	Site 1	Site 2	Site 3	Total
≤18	8	24	0	32
19-40	59	48	77	184
41-65	179	128	165	472
66-95	192	209	87	488
Total	**438**[1]	**409**[2]	**329**[3]	**1176**

[1] All perirectal swabs
[2] 408/409 fresh stool 1/409 perirectal swab
[3] All fresh stool

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Table 3a 18/24 Hours Incubation: Clinical isolates Combined Site performance for Remel Spectra™ ESBL

Overall 18 hr		Reference Method		
		Positive	Negative	Total
Remel Spectra™ ESBL	Positive[1]	201	107	308
	Negative[2]	3	925	928
	Total	204	1032	1236
	Sensitivity	201/204 = 98.5% (95.8-99.5%)[3]		
	Specificity	925/1032 = 89.6% (87.6-91.3%)		
Overall 24 hr		Reference Method		
		Positive	Negative	Total
Remel Spectra™ ESBL	Positive	203	117	320
	Negative	2	914	916
	Total	205	1031	1236
	Sensitivity	203/205 = 99.0% (96.5-99.7%)		
	Specificity	914/1031 = 88.7% (86.6-90.4%)		

[1]Pink, Tan, Blue/Turquoise Green colonies.
[2]Colonies other than Pink, Tan, Blue/Turquoise Green, or No Growth
[3]95% Confidence Interval
Note: For perirectal swabs at both 18 and 24h, sensitivity was 110/111 = 99.1% (94.2-99.8%) and specificity was 313/349 = 89.7% (86.1-92.5%). For stool samples after 18h, sensitivity was 91/93 = 97.8% (92.5-99.4%) and specificity was 612/683 = 89.6% (87.1-91.7%) while after 24h, sensitivity and specificity were 93/94 = 98.9% (94.2-99.8%) and 601/682 = 88.1% (85.5-90.3%) respectively.

Table 3b 18/24 Hours Incubation Organisms recovered on Spectra™ ESBL at Combined sites: comparison of colony color to isolate ID/confirmed ESBL phenotype

Overall 18 hr		Spectra Colony ID and ESBL Phenotype[4]		
		Positive	Negative	Total
Remel Spectra™ ESBL	Positive[1]	203	105[5]	308
	Negative[2]	2	926	928
	Total	205	1031	1236
	PPA	203/205 = 99.0% (96.5-99.7%)[3]		
	NPA	926/1031 = 89.8% (87.8-91.5%)		
Overall 24 hr		Spectra Colony ID and ESBL Phenotype		
		Positive	Negative	Total
Remel Spectra™ ESBL	Positive	206	114[6]	320
	Negative	0	916	916
	Total	206	1030	1236
	PPA	206/206 = 100.0% (98.2-100%)		
	NPA	916/1030 = 88.9% (86.9-90.7%)		

[1]Pink, Tan, Blue/Turquoise Green colonies.
[2]Colonies other than Pink, Tan, Blue/Turquoise Green, or No Growth
[3]95% Confidence Interval
[4] ESBL positive *E. coli*, *K. pneumoniae*, *K. oxytoca* or *P. mirabilis*
[5]104/105 *Enterobacteriaceae* sp.
[6]113/114 *Enterobacteriaceae* sp.

Interfering Substances:
Substances known to be present in fecal samples and/or perirectal swabs were evaluated for potential interference with the growth and/or chromogenic reaction of target organisms on Spectra™ ESBL. The highest concentration of each substance tested in a liquefied stool matrix at which no interference was observed is shown in **Table 4**.

Table 4 Substances evaluated for interference with growth and/or colony color on Spectra™ ESBL

Substance	Concentration at Which No Interference Was Observed
Barium sulfate	1.56 mg/mL [1]
Bisacodyl	50% (w/v) [2]
Blood	5.0% v/v
Fletcher's Castoria	10% v/v
Glycerin	50% (w/v) [2]
Imodium AD®	10% v/v
Kaopectate®	10% v/v
KY Jelly	5.0% w/v [1]
Metronidazole	1.56 mg/mL [1]
Miconazole	5.0% w/v [1]
Mucin	5% (w/v)
Mylanta® ES	0.5% v/v [1]
Nanoxynol-9	50% w/v
Pepcid® AC	0.5% v/v [1, 2]
Pepto-Bismol®	10% v/v
Preparation H®	5.0% w/v [1]
Preparation H® Wipes	5.0% v/v [1]
Prilosec OTC®	1.0% v/v [1, 2]
Tagamet HB 200®	10% v/v [2]
Vancomycin	1.56 mg/mL [1]
Vaseline®	5.0% w/v [1]

[1] Shown to be inhibitory at higher concentration
[2] 1 suppository or tablet dissolved in 10mLPBS, then added to stool

Reproducibility

The reproducibility study of the Spectra™ ESBL was evaluated by testing nine (9) blinded ESBL and Non-ESBL isolates at three (3) sites. The testing occurred over five (5) consecutive work days with at least two (2) operators at each site and using 2 target levels of each panel member (10^4 and 10^6 CFU/mL) to ensure reproducibility and to document proficiency in the performance of the test (i.e. 9 isolates x 2 operators x 5 days x 3 sites). At both target levels there was 100% agreement with expected colony color for all the ESBL-producing organisms (210/210) and there were no false positive results with either of the non-ESBL-producing strains (0/60) (**Table 5**).

Table 5. Reproducibility Study for detection of ESBL producing *E. coli* (3), *K. pneumoniae* (3) and *K. oxytoca* (1) and non ESBL producing *E. coli* (1) and *K. pneumoniae* (1)

	Positive Agreement			Negative Agreement		
	N	Spectra™ ESBL positive	%	N	Spectra™ ESBL Negative	%
Day 1	42	42	100	12	12	100
Day 2	42	42	100	12	12	100
Day 3	42	42	100	12	12	100
Day 4	42	42	100	12	12	100
Day 5	42	42	100	12	12	100
Overall	210	210	100	60	60	100

Reactivity

The ability of Spectra™ ESBL to support growth of ESBL producing organisms was evaluated by testing a total of 48 confirmed ESBL-producing strains: 27 *E. coli*, 8 *K. pneumoniae*, 7 *K. oxytoca* and 6 *P. mirabilis*. Each of the strains grew with the expected colony color when diluted in saline and inoculated on Spectra™ ESBL at a concentration of 10^3 cfu/plate.

Cross Reactivity

One hundred ten (110) microorganisms including 61 strains of confirmed non-ESBL producing *Enterobacteriaceae* and 49 strains of non-*Enterobacteriaceae* species (representing gram negative rods, yeast, fungi, streptococci, enterococci, staphylococci and related organisms) were evaluated with Spectra™ ESBL. Nineteen (19) non-ESBL *Enterobacteriaceae* isolates grew on Spectra™ ESBL, as well as 3 non-*Enterobacteriaceae* (2 *Acinetobacter* spp. and 1 *Pseudomonas aeruginosa*). All the *Enterobacteriaceae* that grew had a typical colony color expected for an ESBL isolate, except for

Salmonella spp., which appeared transparent. Of the 22 isolates that exhibited growth, all but 3 had high cephalosporin MIC's (with or without the clavulanic acid) and would be expected to grow on Spectra™ ESBL. Overall, cross reactivity testing showed that most non-target organisms known to be common fecal flora, will not grow on Spectra™ ESBL. *Acinetobacter* and other non-*Enterobacteriaceae* organisms that grew can be differentiated from target organisms by colony color; however, further testing should be performed on well-isolated pink, blue-turquoise-green or tan colonies obtained on Spectra™ ESBL to confirm ID and ESBL status.

CONCLUSION

The analytical and clinical data demonstrate that Spectra™ ESBL is substantially equivalent to the legally marketed predicate device.