510(k) Summary

510(k) Number: TBD

Date: August 6, 2018

Applicant Information:

Applicant: Microbiologics, Inc.
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St. Cloud, MN 56303

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Device:

Device Trade Name: BD MAX™ CT/GC/TV 20-Day QC Panel
Common Name: Assayed quality control material for clinical microbiology assays
Classification: Class II
Regulation: 21 CFR 866.3920
Panel: 83-Microbiology
Product Code: PMN

Predicate Device:

Bio-Rad Amplichek II (DEN 150058)

Device Description:

The BD MAX™ CT/GC/TV 20-Day QC Panel is used to monitor the extraction, amplification and detection of the BD MAX™ CT/GC/TV Assay. The BD MAX™ CT/GC/TV 20-Day QC Panel contains authentic pathogens inactivated by radiological and temperature treatments. Each BD MAX™ CT/GC/TV 20-Day QC Panel consists of 20 individually packaged positive control pellets in a heat-sealed foil pouch. Each individually packaged pellet consists of inactivated *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* pathogens as well as preservatives and stabilizers. A lyophilized pellet containing inactivated organism(s) is packaged in a 2.0-ml labeled micro-centrifuge tube with a red screw cap.

Device Intended Use:

The BD MAX™ CT/GC/TV 20-Day QC Panel is intended for use as an external assayed positive quality control material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* with the BD MAX™ CT/GC/TV Assay on the BD MAX™ System. The controls comprise cultured and inactivated *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis*.

The BD MAX CT/GC/TV™ 20-Day QC Panel is not intended to replace manufacturer controls provided with the device.

Substantial Equivalence:

Characteristic	**BD MAX™ CT/GC/TV 20-Day QC Panel**	**Predicate Device – Bio-Rad Amplichek II (DEN 150058)**
Intended Use	The BD MAX™ CT/GC/TV 20-Day QC Panel is intended for use as an external assayed positive quality control material to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia*	Amplichek II is intended for use as an external assayed quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of Methicillin Resistant *Staphylococcus aureus*, Methicillin Sensitive *Staphylococcus aureus*,

	trachomatis, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* with the BD MAX™ CT/GC/TV Assay on the BD MAX™ System. The controls comprise cultured and inactivated *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis*. The BD MAX CT/GC/TV™ 20-Day QC Panel is not intended to replace manufacturer controls provided with the device.	*Clostridium difficile* and Vancomycin-resistant Enterococci performed on Cepheid GeneXpert Systems. This product is not intended to replace manufacturer controls provided with the device. This product is only for use with assays and instruments listed in the Representative Results Chart in this labeling.
Physical Format	Lyophilized pellet	Ready-to-use liquid
Composition	Inactivated microorganisms	Inactivated microorganisms
Analytes	*Chlamydia trachomatis* *Neisseria gonorrhoeae* *Trichomonas vaginalis*	Methicillin Resistant *Staphylococcus aureus* Methicillin Sensitive *Staphylococcus aureus* *Clostridium difficile* Vancomycin-resistant Enterococci
Test System	BD MAX System	Cepheid GeneXpert System
Directions for Use	Process like patient sample	Process like patient sample
Assay Steps Monitored	Extraction, amplification, and detection	Extraction, amplification, detection
Number of Targets monitored in one assay	Multiple	Multiple

Summary of Performance Data:

A precision and reproducibility study was conducted to determine device performance. Three different testing locations were used. Six different operators (2 at each facility) and 3 different lots of the BD MAX™ CT/GC/TV 20-Day QC Panel were tested over five days. Each operator performed 3 tests (1 per lot) on 5 different days. All testing was performed on BD MAX™ instruments using the BD MAX™ CT/GC/TV assay.

Analyte	**Agreement (%) by Test Site/BD MAX System**			
	Site 1 [1]	**Site 2** [1]	**Site 3**	**Overall**
C. trachomatis	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
N. gonorrhoeae	30/30 (100)	30/30 (100)	29/30 (97)	89/90 (99)
T. vaginalis	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)

[1]Three Unresolved results were obtained; in all cases a new control was retested and the expected results were obtained

The BD MAX™ CT/GC/TV 20-Day QC Panel does not include a negative control.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.