510(k) Summary

510(k) Number: K190463

Date: March 25, 2019

Applicant Information:

Applicant: Microbiologics, Inc.
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Device:

Device Trade Name: Cepheid Xpert® C. difficile/Epi Control 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:

Cepheid Xpert® GBS LB Control Panel

Device Description:

The Cepheid Xpert® C. difficile/Epi Control Panel is used to monitor DNA extraction, amplification and detection of the Cepheid Xpert® C. difficile/Epi assay. The Cepheid Xpert® C. difficile/Epi Control Panel contains cultured microorganisms inactivated by heat treatments. Each Cepheid Xpert® C. difficile/Epi Control Panel consists of 6 individually packaged positive control swabs and 6 individually wrapped negative control swabs. Each positive control swab contains cultured and inactivated *Clostridioides difficile* at a target level that is designed to provide reproducible performance above the limit of detection of the Cepheid Xpert® C. difficile/Epi assay. The positive control swab is expected to produce positive results for each of the genes targeted by the Cepheid Xpert® C. difficile/Epi assay: toxin B (*tcdB*), binary toxin (CDT) and the variant regulator gene, *tcdC*. Each negative control swab contains *Clostridium sordellii*. Each swab is individually wrapped with a desiccant in a heat-sealed foil pouch.

Device Intended Use:

The Cepheid Xpert® C. difficile/Epi Control Panel is intended for use as external assayed positive and negative quality controls to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Clostridioides (Clostridium) difficile* performed with the Cepheid Xpert® C. difficile/Epi assay on the GeneXpert® Dx System. The controls comprise cultured and inactivated *Clostridioides (Clostridium) difficile* 027-NAP1-B1 as the positive control and *Clostridium sordellii* as the negative control.

The Cepheid Xpert® C. difficile/Epi Control Panel is not intended to replace manufacturer controls provided with the device.

Substantial Equivalence:

Characteristic	**Cepheid Xpert® C. difficile/Epi Control Panel**	**Cepheid Xpert® GBS LB Control Panel (K182472)**
Intended Use	The Cepheid Xpert® C. difficile/Epi Control Panel is intended for use as external	The Cepheid Xpert® GBS LB Control Panel is intended for use as external assayed positive and negative quality

	assayed positive and negative quality controls to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Clostridioides (Clostridium) difficile* performed with the Cepheid Xpert® C. difficile/Epi assay on the GeneXpert® Dx System. The controls comprise cultured and inactivated *Clostridioides (Clostridium) difficile* 027-NAP1-B1 as the positive control and *Clostridium sordellii* as the negative control. The Cepheid Xpert® C. difficile/Epi Control Panel is not intended to replace manufacturer controls provided with the device.	control materials to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of Group B *Streptococcus* (GBS) performed with the Cepheid Xpert® GBS LB Assay on the GeneXpert® Instrument System. The controls comprise cultured and inactivated *Streptococcus agalactiae* as the positive control and *Lactobacillus acidophilus* as the negative control. The Cepheid Xpert® GBS LB Control Panel is not intended to replace manufacturer controls provided with the device.
Physical Format	Lyophilized swab	Lyophilized swab
Composition	Inactivated microorganisms	Inactivated microorganisms
Analytes	*Clostridioides difficile* (*tcdB,* binary toxin, *tcdC*) *Clostridium sordellii*	*Streptococcus agalactiae* *Lactobacillus acidophilus*
Test System	Cepheid GeneXpert® 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

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 Cepheid Xpert® C. difficile/Epi Control Panel were tested over five days. Each operator performed a minimum of 3 tests (1 per lot) on 5 different days. All testing was performed on a GeneXpert® Dx System using the Cepheid Xpert® C. difficile/Epi assay.

Positive Analyte	Agreement (%) by Test Site/GeneXpert® System			
	Site 1	Site 2[1]	Site 3	Overall
Clostridioides difficile (*tcdB*/binary toxin/*tcdC*)	30/30 (100)	31/31 (100)	30/30 (100)	91/91 (100)

1 One ERROR response was observed; a new control was retested and the expected results were obtained.

Negative Analyte	Agreement (%) by Test Site/GeneXpert® System			
	Site 1	Site 2[1]	Site 3	Overall
Clostridium sordellii	30/30 (100)	31/31 (100)	30/30 (100)	91/91 (100)

1 Two ERROR responses were observed; a new control was retested and the expected results were obtained.

Site	Mean Ct (%CV)			
	tcdB	Binary Toxin	*tcdC*	SPC [1]
1	29.5 (2.6)	29.0 (2.5)	28.8 (2.5)	32.7 (2.1)
2	29.7 (2.2)	29.2 (2.1)	29.1 (2.1)	32.3 (1.6)
3	29.3 (1.5)	28.7 (1.6)	28.6 (1.6)	32.5 (2.0)
All Sites	29.5 (2.2)	28.9 (2.2)	28.8 (2.2)	32.5 (2.0)

%CV: Percent Coefficient of Variation; SPC: Sample Processing Control
[1] The values shown for the SPC are only for testing performed with Negative Controls

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