May 8, 2019

Microbiologics, Inc.
Tina Sobania
Director of Corporate Quality
200 Cooper Avenue North
St. Cloud, Minnesota 56303

Re: K190223
Trade/Device Name: Cepheid Xpert CT/NG Control Panel
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed quality control material for clinical microbiology assays
Regulatory Class: Class II
Product Code: PMN
Dated: February 4, 2019
Received: February 5, 2019

Dear Tina Sobania:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part

801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Microbiologics®
A safer, healthier world.
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510(k) Summary

510(k) Number: K190223

Date: May 1, 2019

Applicant Information:

Applicant: Microbiologics, Inc.
Address: 200 Cooper Avenue North
St. Cloud, MN 56303

Primary Contact: Tina Sobania, Director of Corporate Quality
Phone: 320-229-7050
Email: tsobania@microbiologics.com

Device:

Device Trade Name: Cepheid Xpert® CT/NG 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 (K182472)

Device Description:

The Cepheid Xpert® CT/NG Control Panel is used to monitor the extraction, amplification and detection of the Cepheid Xpert® CT/NG Assay. The Cepheid Xpert® CT/NG Control Panel contains authentic pathogens inactivated by radiological or temperature treatments. Each Cepheid Xpert® CT/NG Control Panel consists of 6 individually packaged positive control swabs and 6 individually wrapped negative control swabs. Each positive control swab contains *Chlamydia trachomatis* and *Neisseria gonorrhoeae* as well as preservatives and stabilizers. Each negative control swab contains human cells as well as preservatives and stabilizers. Each swab is individually wrapped with a desiccant in a heat-sealed foil pouch.

Device Intended Use:

The Cepheid Xpert® CT/NG Control Panel is intended for use as an external assayed positive and negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) performed with the Cepheid Xpert® CT/NG assay on the GeneXpert® Instrument System. The controls consist of cultured and inactivated *Chlamydia trachomatis* and *Neisseria gonorrhoeae* as the positive control and human cells as the negative control.

The Cepheid Xpert® CT/NG Control Panel is not intended to replace manufacturer controls provided with the device.

Substantial Equivalence:

Characteristic	**Cepheid Xpert® CT/NG Control Panel**	**Predicate Device – Cepheid Xpert® GBS LB Control Panel (K182472)**
Intended Use	The Cepheid Xpert® CT/NG Control Panel is intended for use as an external assayed positive and negative quality control to monitor	The Cepheid Xpert® GBS LB Control Panel is intended for use as external assayed positive and negative quality control materials to monitor

	the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) performed with the Cepheid Xpert® CT/NG assay on the GeneXpert® System. The controls comprise cultured and inactivated *Chlamydia trachomatis* and *Neisseria gonorrhoeae* as the positive control and human cells as the negative control. The Cepheid Xpert® CT/NG Control Panel is not intended to replace manufacturer controls provided with the device.	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	*Chlamydia trachomatis* *Neisseria gonorrhoeae* Human epithelial cells	*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:

The Cepheid Xpert CT/NG Control Panel was evaluated at three testing sites with two operators at each site (total of six operators). Three lots of the control material were tested with the Cepheid Xpert CT/NG assay on the Cepheid Xpert Instrument, over five days. Each positive and negative control was tested in three replicates on each day. There were seven ERROR results (assay aborted due to instrument or reagent problem) and one INVALID result (failure of the internal control/s). Those samples were retested using a new control swab according to the Instructions for Use. All testing utilized the Xpert Vaginal/Endocervical Swab Specimen Collection kit.

Positive Target	Agreement (%) with Expected Results, by Test Site			
	Site 1 [1,4]	Site 2 [2,4]	Site 3	Overall
C. trachomatis	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
N. gonorrhoeae (NG2)	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
N. gonorrhoeae (NG4)	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)
SPC[3]	31/31 (100)	31/31 (100)	30/30 (100)	92/92 (100)

1 Three ERROR results were observed; in all cases a new control was retested and the expected results were obtained.
2 Two ERROR results and one INVALID result were obtained; in all cases a new control was retested and the expected results were obtained.
3 SPC: Sample Processing Control
4 More than 30 measurements were taken as extra positive controls were ran during re-tests of negative controls.

Negative Target	Agreement (%) with Expected Results, by Test Site			
	Site 1 [1,2,3]	Site 2[2,3]	Site 3	Overall
SAC	33/33 (100)	34/34 (100)	30/30 (100)	97/97 (100)
SPC	33/33 (100)	34/34 (100)	30/30 (100)	97/97 (100)

1 Two ERROR results were observed at Site 1; in all cases a new control was retested and the expected results were obtained.
2 One Negative Control at Site 1 and two Negative Controls at Site 2 generated a positive result for NG2 target, however the qualitative results were negative in each case because the Xpert® CT/NG Assays requires both NG2 and NG4 targets to be positive in order to return a positive result for NG. In accordance with the assay protocol, the work area was cleaned and the controls were retested.
3 More than 30 measurements were taken as extra negative controls were ran during re-tests of positive controls.

Site	Mean Ct (%CV) Positive Control		
	CT1	NG2	NG4
1	31.3 (1.3)	31.2 (1.4)	30.6 (1.5)
2	31.2 (2.6)	31.8 (2.1)	31.1 (2.6)
3	33.0 (3.9)	33.4 (4.1)	32.5 (4.0)
All Sites	31.8 (3.8)	32.1 (4.0)	31.4 (3.9)

%CV: Percent Coefficient of Variation; SPC: Sample Processing Control

Site	Mean Ct (%CV) Negative Control	
	SAC	SPC
1	27.3 (1.8)	31.6 (0.9)
2	27.7 (1.8)	31.4 (0.7)
3	28.8 (4.1)	31.5 (0.5)
All Sites	27.9 (3.5)	31.5 (0.7)

%CV: Percent Coefficient of Variation; SAC: Sample Adequacy Control; SPC: Sample Processing Control

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