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

October, 7 2019

Re: K190086
Trade/Device Name: Cepheid Xpert Respiratory 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: September 12, 2019
Received: September 13, 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tamara Feldblyum, M.S., Ph.D.
Chief,
Viral Respiratory and STI Branch
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

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510(k) Summary

510(k) Number: K190086

Date: September 19, 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® Respiratory 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® Respiratory Control Panel is used to monitor RNA extraction, amplification and detection of the Cepheid Xpert® Xpress Flu/RSV assay. The Cepheid Xpert® Respiratory Control Panel contains cultured viruses inactivated by chemical or radiological treatments. Each Cepheid Xpert® Respiratory Control Panel consists of 6 individually packaged positive control swabs and 6 individually wrapped negative control swabs. Each positive control swab contains Influenza A (H1N1) virus, Influenza A (H3N2) virus, Influenza B virus and Respiratory syncytial virus A. Each negative control swab contains Coxsackie B1 virus. Each swab is individually wrapped with a desiccant in a heat-sealed foil pouch.

Device Intended Use:

The Cepheid Xpert® Respiratory 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 Influenza A (H1N1) virus, Influenza A (H3N2) virus, Influenza B virus and Respiratory Syncytial Virus A performed with the Cepheid Xpert® Xpress Flu/RSV assay on the GeneXpert® Instrument System. The controls comprise cultured and inactivated Influenza A (H1N1) virus, Influenza A (H3N2) virus, Influenza B virus and Respiratory Syncytial Virus A as the positive control and Coxsackie virus B1 as the negative control.

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

Substantial Equivalence:

Characteristic	**Cepheid Xpert® Respiratory Control Panel**	**Predicate Device Cepheid Xpert® GBS LB Control Panel (K182472)**
Intended Use	The Cepheid Xpert® Respiratory Control Panel is intended for us as an external assayed positive and negative quality control to monitor the	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 Influenza A (H1N1) virus, Influenza A (H3N2) virus, Influenza B virus and Respiratory Syncytial Virus A performed with the Cepheid Xpert® Xpress Flu/RSV assay on the GeneXpert® Instrument System. The controls comprise cultured and inactivated Influenza A (H1N1) virus, Influenza A (H3N2) virus, Influenza B virus and Respiratory Syncytial Virus A as the positive control and Coxsackie virus B1 as the negative control. The Cepheid Xpert® Respiratory Control Panel is not intended to replace manufacturer controls provided with the device.	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	Influenza A (H1N1) virus Influenza A (H3N2) virus Influenza B virus Respiratory Syncytial Virus A Coxsackie virus B1	*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 performance of the Cepheid Xpert® Respiratory Control Panel was evaluated in a study that was performed using three different production lots, three sites, using three different GeneXpert® Instrument Systems and six different users. The results of the study are summarized below.

Positive Analyte	Agreement (%) by Test Site/GeneXpert® System			
	Site 1	Site 2	Site 3[1]	Overall
Influenza A (H1N1)	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
Influenza A (H3N2)	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
Influenza B	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
Respiratory Syncytial Virus A	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)

1 One NO RESULT response was observed; a new control was retested and the expected results were obtained.

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Negative Analyte	Agreement (%) by Test Site/GeneXpert® System			
	Site 1	Site 2	Site 3	Overall
Coxsackievirus B1	30/30 (100)	30/30 (100)	31/31 (100)	91/91 (100)

Conclusion

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