November 8, 2018

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

Re: K182472
Trade/Device Name: Cepheid Xpert GBS LB 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 5, 2018
Received: September 10, 2018

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,

Steven R. Gitterman -S 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182472

Device Name
Cepheid Xpert® GBS LB Control Panel

Indications for Use *(Describe)*
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 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.

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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200 Cooper Avenue North
Saint Cloud, Minnesota 56303 USA
www.microbiologics.com

510(k) Summary

510(k) Number: K182472

Date: October 18, 2018

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® GBS LB 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:

Bio-Rad Amplichek II (DEN 150058)

Device Description:

The Cepheid Xpert® GBS LB Control Panel is used to monitor the extraction, amplification and detection of the Cepheid Xpert® GBS LB Assay. The Cepheid Xpert® GBS LB Control Panel contains authentic pathogens inactivated by temperature treatments. Each Cepheid Xpert® GBS LB Control Panel consists of 6 individually packaged positive control swabs and 6 individually wrapped negative control swabs. Each positive control swab contains *Streptococcus agalactiae* (Lancefield's Group B) as well as preservatives and stabilizers. Each negative control swab contains *Lactobacillus acidophilus* 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® 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 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.

Substantial Equivalence:

Characteristic	**Cepheid Xpert® GBS LB Control Panel**	**Predicate Device – Bio-Rad Amplichek II (DEN 150058)**
Intended Use	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	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

	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.	of Methicillin Resistant *Staphylococcus aureus*, Methicillin Sensitive *Staphylococcus aureus*, *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 swab	Ready-to-use liquid
Composition	Inactivated microorganisms	Inactivated microorganisms
Analytes	*Streptococcus agalactiae* *Lactobacillus acidophilus*	Methicillin Resistant *Staphylococcus aureus* Methicillin Sensitive *Staphylococcus aureus* *Clostridium difficile* Vancomycin-resistant Enterococci
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® GBS LB Control Panel were tested over five days. Each operator performed 3 tests (1 per lot) on 5 different days. All testing was performed on a GeneXpert® Instrument System using the Cepheid Xpert® GBS LB Assay.

Analyte	Agreement (%) by Test Site/ GeneXpert® Instrument System			
	Site 1 [1]	Site 2	Site 3	Overall
S. agalactiae	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)
L. acidophilus	30/30 (100)	30/30 (100)	30/30 (100)	90/90 (100)

[1]One ERROR result was obtained; a new control was retested and the expected results were obtained

Conclusion

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