June 25, 2019

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

Re: K191168
Trade/Device Name: Cepheid Xpert SA Nasal Complete 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: April 30, 2019
Received: May 1, 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,

for

Uwe Scherf, M.Sc., 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: K191168

Date: June 10, 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® SA Nasal Complete 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® SA Nasal Complete Control Panel is used to monitor the DNA extraction, amplification and detection processes of the Cepheid Xpert® SA Nasal Complete Assay. The Cepheid Xpert® SA Nasal Complete Control Panel contains cultured microorganisms inactivated by heat treatments. Each Cepheid Xpert® SA Nasal Complete Control Panel consists of 6 individually packaged Methicillin-Resistant *Staphylococcus aureus* (MRSA) positive control swabs (positive control 1); 6 individually wrapped *Staphylococcus aureus* (MSSA) positive controls swabs (positive control 2); and 6 individually wrapped negative control swabs. Each positive control 1 swab contains MRSA at a target level that is designed to provide reproducible performance above the limit of detection for each of the genes targeted by the Cepheid Xpert® SA Nasal Complete Assay: Staphylococcal protein A gene *spa* (SPA), methicillin resistance gene *mecA* (mec), and the Staphylococcal cassette chromosome (SCC). Each positive control 2 swab contains MSSA at a target level designed to provide reproducible performance above the limit of detection of the *spa* gene target of the Cepheid Xpert® SA Nasal Complete Assay. Each negative control swab contains *Staphylococcus epidermidis* (MSSE) which is methicillin susceptible and not detected by the Cepheid Xpert® SA Nasal Complete Assay. Each swab is individually wrapped with a desiccant in a heat-sealed foil pouch.

Device Intended Use:

The Cepheid Xpert® SA Nasal Complete 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 Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA) performed with the Cepheid Xpert® SA Nasal Complete Assay on the GeneXpert® Dx System. The controls comprise cultured and inactivated Methicillin-Resistant *Staphylococcus aureus* as the positive control 1; *Staphylococcus aureus* as the positive control 2; *Staphylococcus epidermidis* as the negative control.

The Cepheid Xpert® SA Nasal Complete Control Panel is not intended to replace manufacturer controls provided with the Cepheid Xpert® SA Nasal Complete Assay.

Substantial Equivalence:

Characteristic	**Cepheid Xpert® SA Nasal Complete Control Panel**	**Cepheid Xpert® GBS LB Control Panel (K182472)**
Intended Use	The Cepheid Xpert® SA Nasal Complete 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 Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA) performed with the Cepheid Xpert® SA Nasal Complete Assay on the GeneXpert® Dx System. The controls comprise cultured and inactivated Methicillin-Resistant *Staphylococcus aureus* as the positive control 1; *Staphylococcus aureus* as the positive control 2; *Staphylococcus epidermidis* as the negative control. The Cepheid Xpert® SA Nasal Complete Control Panel is not intended to replace manufacturer controls provided with the Cepheid Xpert® SA Nasal Complete Assay.	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.
Physical Format	Lyophilized swab	Lyophilized swab
Composition	Inactivated microorganisms	Inactivated microorganisms
Analytes	Methicillin-Resistant *Staphylococcus aureus* *Staphylococcus aureus* *Staphylococcus epidermidis*	*Streptococcus agalactiae* *Lactobacillus acidophilus*
Test System	Cepheid GeneXpert® Dx System	Cepheid GeneXpert® Instrument 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® SA Nasal Complete 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® SA Nasal Complete Assay.

Positive Analyte	**Agreement (%) by Test Site/GeneXpert® System**				
Location	**Site 1**	**Site 2**	**Site 3[1]**		**Overall Correct Result**
Assay Response	**Correct Result**	**Correct Result**	**Correct Result**	**NO RESULT**	
Methicillin-Resistant *Staphylococcus aureus* (SPA, mec, SCC)	30/30 (100)	30/30 (100)	30/30 (100)	1	90/90 (100)
Staphylococcus aureus (SPA)	30/30 (100)	30/30 (100)	30/30 (100)	2	90/90 (100)

1 Three NO RESULT responses were observed; new controls were retested and the expected results were obtained.

Negative Analyte	Agreement (%) by Test Site/GeneXpert® System								
Location	Site 1[1]		Site 2[1,3]			Site 3[1,2]			Overall Correct Result
Assay Response	Correct Result	INVALID	Correct Result	INVALID	ERROR	Correct Result	INVALID	NO RESULT	
Staphylococcus epidermidis	30/30 (100)	8[4]	30/30 (100)	2	1	30/30 (100)	4	1	90/90 (100)

1 Multiple INVALID responses were observed; new controls were retested and the expected results were obtained.
2 One NO RESULT response was observed; a new control was retested and the expected results were obtained.
3 One ERROR response was observed; a new control was retested, and the expected results were obtained.
4 Eight INVALID responses from single user.

Site	6027 Mean Ct (%CV)		
	SPA	mec	SCC
1	27.0 (2.7)	27.3 (2.6)	28.5 (2.3)
2	28.1 (2.3)	28.4 (2.0)	29.6 (1.9)
3	27.8 (2.2)	28.1 (2.1)	29.3 (2.1)
All Sites	27.6 (3.0)	27.9 (2.8)	29.1 (2.7)

%CV: Percent Coefficient of Variation

Site	6028 Mean Ct (%CV)
	SPA
1	26.8 (2.7)
2	27.8 (2.5)
3	27.4 (2.8)
All Sites	27.3 (3.0)

%CV: Percent Coefficient of Variation

Site	6029 Mean Ct (%CV)
	SPC
1	32.0 (4.2)
2	31.8 (3.5)
3	32.1 (4.4)
All Sites	32.0 (4.0)

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

Conclusion

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