



October 21, 2019

GeneOhm Sciences Canada, Inc. (BD Diagnostics)

Katie Edwards

Regulatory Affairs Project Manager

2555 Boul. du Parc-Technologique

Quebec, GIP 4S5 Ca

Re: K191957

Trade/Device Name: BD MAX Vaginal Panel, BD MAX System

Regulation Number: 21 CFR 866.3975

Regulation Name: Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis

Regulatory Class: Class II

Product Code: PQA, OUY, OOI, NSU

Dated: July 22, 2019

Received: July 23, 2019

Dear Katie Edwards:

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,

Kristian Roth, Ph.D.
Branch Chief
Bacterial Multiplex and Medical Counter Measures
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

510(k) Summary

BD MAX Vaginal Panel

Summary Preparation Date:

9/26/2019

Submitted by:

BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

Katie Edwards
Regulatory Affairs Project Manager

Tel: 410-316-4975

Email: Katie_Edwards@bd.com

Proprietary Names:

For the instrument:

BD MAX™ System

For the assay:

BD MAX™ Vaginal Panel

Common Names:

For the instrument:

Bench-top molecular diagnostics workstation

Regulatory Information

Regulation section:

21 CFR 866.3975 – Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis

Classification:

Class II (Special Controls)

Panel:

Microbiology (83)

Product Code(s):

PQA Vaginitis and Bacterial Vaginosis Nucleic Acid Detection System

OUY *Trichomonas vaginalis* Nucleic Acid Amplification Test System

OOI Real Time Nucleic Acid Amplification System

NSU Instrumentation for Clinical Multiplex Test Systems

Predicate Device

BD MAX Vaginal Panel (DEN160001)

Performance Standards

Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of *Trichomonas vaginalis*, August 4, 2015.

Intended Use

The BD MAX Vaginal Panel performed on the BD MAX System is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and quantitation of targeted organism markers), *Candida* species associated with vulvovaginal candidiasis, and *Trichomonas vaginalis* from vaginal swabs in patients who are symptomatic for vaginitis/vaginosis. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from:

- Bacterial vaginosis markers (Individual markers not reported)
 - Lactobacillus* spp. (*L. crispatus* and *L. jensenii*)
 - Gardnerella vaginalis*
 - Atopobium vaginae*
 - Bacterial Vaginosis Associated Bacteria-2 (BVAB-2)
 - Megasphaera-1*
- *Candida* spp. (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. dubliniensis*)
- *Candida glabrata*
- *Candida krusei*
- *Trichomonas vaginalis*

The BD MAX Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.

Special Conditions for Use Statement: For Prescription Use Only

Special Instrument Requirements: The BD MAX Vaginal Panel is performed on the BD MAX System.

Device Description

The BD MAX System and the BD MAX Vaginal Panel are comprised of an instrument with associated hardware and accessories, disposable microfluidic cartridges, master mixes, unitized reagent strips, and extraction reagents. The instrument automates sample preparation including target lysis, DNA extraction and concentration, reagent rehydration, target nucleic acid amplification and detection using real-time PCR. The assay includes a Sample Processing Control (SPC) that is present in the Extraction Tube. The SPC monitors DNA extraction steps, thermal cycling steps, reagent integrity and the presence of inhibitory substances. The BD MAX System software automatically interprets test results. For the BD MAX Vaginal Panel, a test result may be called as POS, NEG or UNR (Unresolved) based on the

amplification status of the targets and of the Sample Processing Control. IND (Indeterminate) or INC (Incomplete) results are due to BD MAX System failure.

Test Principle

The BD MAX Vaginal Panel is designed for use with the BD MAX™ UVE Specimen Collection kit. Samples are transported to the testing laboratory in BD MAX UVE Sample Buffer Tubes (SBT). The Sample Buffer Tubes, are vortexed to release cells from the swab into the buffer. The Sample Buffer Tubes, Unitized Reagent Strips and PCR Cartridges are loaded on the BD MAX System. No further operator intervention is necessary and the following automated procedures occur.

A combination of lytic and extraction reagents are used to perform cell lysis and DNA extraction. Nucleic acids released from the target organisms are captured on magnetic affinity beads. The beads, together with the bound nucleic acids, are washed and the nucleic acids are eluted by a combination of heat and pH. Eluted DNA is neutralized and transferred to the Master Mix Tubes to rehydrate the PCR reagents. After reconstitution, the BD MAX System dispenses a fixed volume of PCR-ready solution containing extracted nucleic acids into the PCR Cartridge. Microvalves in the cartridge are sealed by the system prior to initiating PCR in order to contain the amplification mixture and thus prevent evaporation and contamination.

The amplified DNA targets are detected using hydrolysis probes, labeled at one end with a fluorescent reporter dye (fluorophore), and at the other end, with a quencher moiety. Probes labeled with different fluorophores are used to detect the target analytes in different optical channels of the BD MAX System. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target DNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'-3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the DNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The amount of fluorescence detected in the optical channels used for the BD MAX Vaginal Panel is directly proportional to the quantity of the corresponding probe that is hydrolyzed. The BD MAX System monitors these signals at each cycle of the PCR and interprets the data at the end of the reaction to provide qualitative test results for each vaginitis analyte as well as qualitative results for bacterial vaginosis based on detection and quantitation of targeted bacterial vaginosis markers.

Technological Characteristics

<i>Items</i>	<i>BD MAX Vaginal Panel (modified)</i>	<i>BD MAX Vaginal Panel (DEN160001)</i>
Regulation	866.3975	
Product Code	PQA	
Device Class	II	
Intended Use	The BD MAX Vaginal Panel performed on the BD MAX System is an automated qualitative in vitro diagnostic test for the direct detection of DNA targets from bacteria associated with bacterial vaginosis (qualitative results reported based on detection and quantitation of targeted organism markers), <i>Candida</i> species associated with vulvovaginal candidiasis, and <i>Trichomonas vaginalis</i> from vaginal swabs in patients who are symptomatic for vaginitis/vaginosis. The test utilizes real-time polymerase chain reaction (PCR) for the amplification of specific DNA targets and utilizes fluorogenic target-specific hybridization probes to detect and differentiate DNA from: • Bacterial vaginosis markers (Individual markers not reported)	

	- <i>Lactobacillus</i> spp. (<i>L. crispatus</i> and <i>L. jensenii</i>) - <i>Gardnerella vaginalis</i> - <i>Atopobium vaginae</i> - Bacterial Vaginosis Associated Bacteria-2 (BVAB-2) - <i>Megasphaera-1</i> • <i>Candida</i> spp. (<i>C. albicans</i>, <i>C. tropicalis</i>, <i>C. parapsilosis</i>, <i>C. dubliniensis</i>) • <i>Candida glabrata</i> • <i>Candida krusei</i> • <i>Trichomonas vaginalis</i> The BD MAX Vaginal Panel is intended to aid in the diagnosis of vaginal infections in women with a clinical presentation consistent with bacterial vaginosis, vulvovaginal candidiasis and trichomoniasis.	
Indications for Use	Symptomatic patients	
Specimen Type	Clinician and patient-collected female vaginal swab	
Technology	PCR	
Organisms Detected	• Bacterial vaginosis markers (<i>Lactobacillus</i> spp., <i>Gardnerella vaginalis</i>, <i>Atopobium vaginae</i>, BVAB-2, <i>Megasphaera-1</i>) • <i>Candida</i> spp. • <i>Candida glabrata</i> • <i>Candida krusei</i> • <i>Trichomonas vaginalis</i>	
Sample Prep / Interpretation of Results	Automated by BD MAX System	
Assay Controls	Sample Processing Control	
Collection / Transport Device	MAX UVE Specimen Collection Kit	
Interpretation of Result	Qualitative	
Software	ADF version 3.0	ADF version 2.0

Conclusions

Conclusions drawn from the risk-based assessment demonstrate that the device is substantially equivalent and performs as well as the legally marketed device identified above.