GeneOhm Sciences Canada, Inc. (BD Life Sciences)
Susan Werner
Director, Regulatory Affairs
2555 Boul. Du Parc-Technologique
Quebec, QC G1P4S5
Canada

October 18, 2021

Re: K201017
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
Dated: April 16, 2020
Received: April 17, 2020

Dear Susan Werner:

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.
Deputy 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

Indications for Use Statement

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)*

Device Name
BD MAX™ Vaginal Panel

Indications for Use *(Describe)*

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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

BD MAX™ Vaginal Panel

Summary Preparation Date:

10/18/2021

Submitted by:

BD Life Sciences
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 and K191957)

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:

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  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 Molecular Swab Collection kit. Samples are transported to the testing laboratory in BD Molecular Swab Sample Buffer Tubes. 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.

Substantial Equivalence

Table 1 provides the similarities and differences between the submitted device and the legally marketed predicate device.

Table 1: Comparison to Predicate Device

Items	***BD MAX Vaginal Panel (Submitted Device)***	***BD MAX Vaginal Panel (DEN160001)***
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.	
Specimen Type	Clinician and patient-collected female vaginal swab	
Collection / Transport Device	BD Molecular Swab Collection Kit	BD MAX UVE Specimen Collection Kit
Same Buffer Formulation	Potassium phosphate, EDTA, Tween 20 and Proclin buffer	
Sample Buffer Volume	2.0 mL	1.5 mL
Swab Type	Polyester	
Sterilization Method	Irradiation	
Bud Size	0.156 in	0.125 in
Fiber Composition	Polyester	
Shaft Composition	Polystyrene	

Performance Evaluation:

Three studies were conducted to demonstrate the substantial equivalence between the BD Molecular Swab Collection Kit (previously cleared for use with the BD MAX Vaginal Panel) and the BD MAX UVE Specimen Collection Kit:

- Confirmation of equivalent analytical sensitivity with the BD Molecular Swab Collection Kit by the limiting dilution LoD model. Limiting dilutions of specimens tested using the BD MAX UVE Specimen Collection Kit and the BD Molecular Swab Collection Kit exhibited drop-out rates at similar levels when tested using the BD MAX Vaginal Panel on the BD

MAX System. There was no indication that the new collection device negatively impacted the analytical sensitivity of the BD MAX Vaginal Panel.

- Comparison study of performance between the cleared collection device and the new collection device tested with the BD MAX Vaginal Panel on the BD MAX System with clinical specimens demonstrated PPA point estimates 96.9%, 87.8%, and 97.1% for bacterial vaginosis, *Candida* species and *Trichomonas vaginalis*, respectively. Further statistical analysis of the PCR metrics demonstrated that specimens collected with the BD Molecular Swab Collection Kit are not significantly different from specimens collected using the BD MAX UVE Specimen Collection Kit as the two collection kits demonstrate similar performance when used for collection of vaginal specimens that are then tested with the BD MAX Vaginal Panel.
- A stability study was carried out in accordance with a predefined protocol for both Bacterial Vaginosis and Vaginitis, using the BD Max Vaginal Panel Assay and BD Molecular Swab Collection Kit. This study demonstrated the stability of Bacterial Vaginosis and Vaginitis targets stored in BD Molecular Swab Sample Buffer Tube (non-pierced) – Up to 21 days at 2-30ºC and in BD Molecular Swab Sample Buffer Tube(after the cap is pierced)- Up to 4 days at 2-30ºC.

Conclusion

The studies conducted support that the modified device, BD MAX Vaginal Panel on the BD MAX System is substantially equivalent to the predicate device.