



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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GeneOhm Sciences Canada, Inc. (BD Diagnostics)
C/O Patricia Dionne, Ph.D., MBA.
Director Regulatory Affairs
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October 28, 2016

Re: DEN160001
BD Max Vaginal Panel
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 866.3975
Regulation Name: Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis
Regulatory Classification: Class II
Product Code: PQA, OUY, OOI, NSU
Dated: January 11, 2016
Received: January 12, 2016

Dear Dr. Dionne:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of BD Max Vaginal Panel, a prescription device. The indications for use of the BD Max Vaginal Panel is:

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.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies BD Max Vaginal Panel, and substantially equivalent devices of this generic type, into class II under the generic name, “Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis.”

FDA identifies this generic type of device as: Device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis.

A device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis is a qualitative *in vitro* device intended for the detection of microbial nucleic acid sequences in vaginal specimens collected from patients with signs and symptoms of vaginitis or bacterial vaginosis. This device is intended to aid in the diagnosis of vaginitis or bacterial vaginosis when used in conjunction with clinical signs and symptoms and other laboratory findings.

Section 513(f)(2) of the Food, Drug & Cosmetic Act (FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the FD&C Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the FD&C Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On January 12, 2016, FDA received your *de novo* request for classification of the BD Max Vaginal Panel. The petition was submitted under section 513(f)(2) of the FD&C Act. In order to classify the BD Max Vaginal Panel into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the BD Max Vaginal Panel indicated for use as follows

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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can be classified in class II with the establishment of special controls for this type of device. FDA believes that the class II special controls identified later in this order, along with the applicable general controls, including the design controls under 21 CFR part 820, provide reasonable assurance of the safety and effectiveness of the device type.

Table 1 – Identified Risks and Identified Mitigations

Identified Risks to Health	Identified Mitigations
Incorrect identification or lack of identification of a pathogenic microorganism by the device can lead to improper patient management	General controls and special controls (1), (2), (3), and (4)
Failure to correctly interpret test results	General controls and special controls (5), (6), (7), and (8)

In combination with the general controls of the FD&C Act, a device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis is subject to the following special controls:

- 1) Premarket notification submissions must include a detailed device description of the following:
 - a. Device components;
 - b. Ancillary reagents required but not provided; and

- c. Explanation of the methodology including primer/probe sequence, design, and rationale for sequence selection.
- 2) Premarket notification submissions must include information that demonstrates the performance characteristics of the device, including:
 - a. Limit of Detection;
 - b. Precision (reproducibility);
 - c. Analytical specificity;
 - d. Analytical reactivity (inclusivity);
 - e. Specimen stability; and
 - f. Effects of interfering substances.
- 3) Premarket notification submissions must include detailed documentation from a prospective clinical study. As appropriate to the intended use, the prospective clinical study must be performed on an appropriate study population including women of various ages and ethnicities. The prospective clinical study must compare the device performance to results obtained from well-accepted comparator methods.
- 4) Premarket notification submissions must include detailed documentation for device software, including, but not limited to, software applications and hardware-based devices that incorporate software.
- 5) A detailed explanation of the interpretation of results and acceptance criteria must be included in the device's 21 CFR 809.10(b)(9) compliant labeling.
- 6) For indications for use that include detection of nucleic acid sequences from bacteria associated with bacterial vaginosis, the 21 CFR 809.10(b)(12) compliant labeling must include clinical performance stratified by patient demographics such as race, ethnicity, age, and pregnancy status.
- 7) For indications for use that include detection of nucleic acid sequences from bacteria associated with bacterial vaginosis, the 21 CFR 809.10(b)(12) compliant labeling must include a summary of device results in an asymptomatic population with demographic characteristics appropriate to the intended use population.
- 8) For indications for use that include detection of either *Candida* species or bacteria associated with bacterial vaginosis, the 21 CFR 809.10 compliant labeling must include a limitation that *Candida* species and bacterial compositions associated with bacterial vaginosis can be present as part of normal vaginal flora and results should be considered in conjunction with available clinical information.

In addition, this is a prescription device. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide a reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket

notification containing information on the device that detects nucleic acid sequences from microorganisms associated with vaginitis and bacterial vaginosis they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Kimberly Sconce at 301-796-6679.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director
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