February 2, 2022

Zeptometrix
℅ Michael Smith
Manager, Regulatory and Clinical Affairs
MDC Associates Inc.
180 Cabot Street
Beverly, Massachusetts 01915

Re: K201403
Trade/Device Name: NATtrol Vaginal Panel External Run Controls
Regulation Number: 21 CFR 866.3920
Regulation Name: Assayed Quality Control Material For Clinical Microbiology Assays
Regulatory Class: Class II
Product Code: PMN
Dated: May 26, 2020
Received: May 28, 2020

Dear Michael Smith:

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

Maria Garcia, Ph.D.
Branch Chief
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

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)*
K201403

Device Name
NATtrol™ BD MAX Vaginal Panel External Controls

Indications for Use *(Describe)*
NATtrol™ BV Negative Control (NATBVNEG-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol BV Negative Control is a qualitative control containing intact and inactivated Lactobacillus crispatus and intended to be used solely with the BD Vaginal Panel for BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert.

NATtrol™ BV Positive Control (NATBVPOS-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol™ BV Positive Control is a qualitative control containing intact and inactivated Lactobacillus jensenii, Gardnerella vaginalis, Atopobium vaginae, and Saccharomyces cerevisiae containing BVAB2 (Bacterial Vaginosis-Associated Bacterium 2) sequence and intended to be used solely with the BD Vaginal Panel for BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert.

NATtrol™ Candida/TV Positive Control (NATCTVPOS-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol Candida/TV Positive Control is a qualitative control containing intact and inactivated Candida albicans, Candida krusei, Candida glabrata, and Trichomonas vaginalis and intended to be used solely with the BD Vaginal Panel for the BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert.

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

Date of Summary: November 12, 2021

Product Name: NATtrol™ BD MAX Vaginal Panel External Controls

Sponsor:
ZeptoMetrix, LLC
878 Main Street
Buffalo, NY. 14202

Correspondent:
MDC Associates, Inc.
Michael Smith, Manager, Regulatory and Clinical Affairs
180 Cabot Street
Beverly, MA 01915
Phone: (978) 927 3808
Fax: (866) 540 3448
Email: regulatory@mdcassoc.com

Common Name: Assayed quality control material for clinical microbiology assays.

Regulation Number: 866.3920

Classification: Class II

Predicate Device: Microbiologics, Inc. BD MAX CT/GC/TV 20-Day QC Panel (K181683)

Substantial Equivalency

Description	**ZeptoMetrix Corporation** **NATtrol™ BD MAX Vaginal Panel External Controls** (New Device)	**Microbiologics, Inc.** **BD MAX CT/GC/TV 20-Day QC Panel** K181683 (Predicate Device)
	Similarities	
Intended Use	NATtrol™ BV Negative Control (NATBVNEG-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol BV Negative Control is a qualitative control containing intact and inactivated *Lactobacillus crispatus* and intended to be used solely with the BD Vaginal Panel for BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert. NATtrol™ BV Positive Control (NATBVPOS-BD) is intended for use as an assayed	The BD MAX CT/GC/TV 20-Day QC Panel is intended for use as an external assayed positive quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the qualitative detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae* and *Trichomonas vaginalis* with the BD MAX CT/GC/TV Assay on the BD MAX System. The controls comprise cultured and inactivated *C. trachomatis*, *N. gonorrhoeae* and *T. vaginalis*. The BD MAX CT/GC/TV 20-Day QC Panel is not intended to replace manufacturer controls provided with the device.

Description	ZeptoMetrix Corporation **NATtrol™ BD MAX Vaginal Panel External Controls** (New Device)	**Microbiologics, Inc.** **BD MAX CT/GC/TV 20-Day QC Panel** K181683 (Predicate Device)
	quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol™ BV Positive Control is a qualitative control containing intact and inactivated *Lactobacillus jensenii, Gardnerella vaginalis, Atopobium vaginae*, and *Saccharomyces cerevisiae* containing BVAB2 (Bacterial Vaginosis-Associated Bacterium 2) sequence and intended to be used solely with the BD Vaginal Panel for BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert. NATtrol™ Candida/TV Positive Control (NATCTVPOS-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol Candida/TV Positive Control is a qualitative control containing intact and inactivated *Candida albicans, Candida krusei, Candida glabrata*, and *Trichomonas vaginalis* and intended to be used solely with the BD Vaginal Panel for the BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert.	
Composition	Inactivated microorganisms	Same
Test system	BD MAX System	Same
Assay Steps Monitored	Extraction, amplification and detection	Same
Analytes	Inactivated microorganisms	Same
Differences		
Physical Format	Ready-to-use liquid	Lyophilized pellet
Number of Targets Monitored	8	3

Intended Use

NATtrol™ BV Negative Control (NATBVNEG-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol BV Negative Control is a qualitative control containing intact and inactivated *Lactobacillus crispatus* and intended to be used solely with the BD Vaginal Panel for BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert.

NATtrol™ BV Positive Control (NATBVPOS-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol™ BV Positive Control is a qualitative control containing intact and inactivated *Lactobacillus jensenii*, *Gardnerella vaginalis*, *Atopobium vaginae*, and *Saccharomyces cerevisiae* containing BVAB2 (Bacterial Vaginosis-Associated Bacterium 2) sequence and intended to be used solely with the BD Vaginal Panel for BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert.

NATtrol™ Candida/TV Positive Control (NATCTVPOS-BD) is intended for use as an assayed quality control material to monitor the performance of in vitro diagnostic laboratory nucleic acid testing procedures for the qualitative detection of targets on the BD Vaginal Panel for BD MAX™ System. NATtrol Candida/TV Positive Control is a qualitative control containing intact and inactivated *Candida albicans*, *Candida krusei*, *Candida glabrata*, and *Trichomonas vaginalis* and intended to be used solely with the BD Vaginal Panel for the BD MAX™ System. This product is not intended to replace manufacturer controls provided in the package insert.

Test Principle

Not applicable; this is control material to monitor performance of a test.

Device Description

NATtrol™ BD MAX Vaginal Panel External Controls are formulated with purified, intact microorganisms that have been chemically modified to render them non-infectious and refrigerator stable. The controls are formulated in a proprietary matrix that contains Fetal Bovine Serum, Human Serum Albumin, and sodium azide.

NATtrol™ BV Positive Control contains intact and inactivated *Lactobacillus jensenii*, *Gardnerella vaginalis*, *Atopobium vaginae*, and *Saccharomyces cerevisiae* containing BVAB2 (Bacterial Vaginosis-Associated Bacterium 2) sequence.

NATtrol™ *Candida*/TV Positive Control contains intact and inactivated *Candida albicans*, *Candida krusei*, *Candida glabrata*, and *Trichomonas vaginalis*.

NATtrol™ BV Negative Control contains intact and inactivated *Lactobacillus crispatus*.

Performance Data

A single site performance study was conducted to evaluate precision and performance of the NATtrol™ BD MAX Vaginal Panel External Controls. The Performance of the controls was evaluated by observing the data collected during multiple studies performed by six (6) operators using two (2) lots of BV Positive, two (2) lots of BV Negative and one (1) lot of Candida/TV Positive controls.

-	BV Positive Control	
Target	**BD MAX Result (Observed/Total)**	**% Agreement with expected Results (95% CI)**
BV	Positive (84/86)	97.7% (91.9%-99.4%)
C group	Negative (86/86)	100% (95.7%-100%)
C. krusei	Negative (86/86)	100% (95.7%-100%)
C. glabrata	Negative (86/86)	100% (95.7%-100%)
TV	Negative (86/86)	100% (95.7%-100%)

-	Candida/TV Positive Control	
Target	**BD MAX Result (Observed/Total)**	**% Agreement with expected Results (95% CI)**
BV	Negative (102/104)	98.1% (93.3%-99.5%)
C group	Positive (103/104)	99.0% (94.8%-99.8%)
C. krusei	Positive (103/104)	99.0% (94.8%-99.8%)
C. glabrata	Positive (103/104)	99.0% (94.8%-99.8%)
TV	Positive (103/104)	99.0% (94.8%-99.8%)

-	BV Negative Control	
Target	**BD MAX Result (Observed/Total)**	**% Agreement with expected Results (95% CI)**
BV	Negative (191/191)	100% (98.0%-100%)
C group	Negative (189/191)	99.0% (96.3%-99.7%)
C. krusei	Negative (191/191)	100% (98.0%-100%)
C. glabrata	Negative (191/191)	100% (98.0%-100%)
TV	Negative (191/191)	100% (98.0%-100%)

Conclusion

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