August 19, 2022

Becton, Dickinson and Company
Joseph Basore
Staff Regulatory Affairs Specialist
7 Loveton Circle
Sparks, Maryland 21152

Re: K220193
Trade/Device Name: BD MAX Enteric Parasite Panel
Regulation Number: 21 CFR 866.3990
Regulation Name: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assay
Regulatory Class: Class II
Product Code: PCH, OOI
Dated: January 21, 2022
Received: January 24, 2022

Dear Joseph Basore:

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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220193

Device Name
BD MAX Enteric Parasite Panel

Indications for Use *(Describe)*

The BD MAX Enteric Parasite Panel performed on the BD MAX System is an automated in vitro diagnostic test for the direct qualitative detection of enteric parasitic pathogens. The BD MAX Enteric Parasite Panel detects nucleic acids from:

Giardia lamblia
Cryptosporidium (C. hominis and C. parvum only),
Entamoeba histolytica

Testing is performed on unpreserved or 10% formalin-fixed stool specimens or FecalSwab specimens from symptomatic patients with suspected gastroenteritis, enteritis, or colitis. The assay is intended to aid in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation and other laboratory findings. The test is performed directly on the specimen, utilizing real- time polymerase chain reaction (PCR) for the amplification of specific targets. The test utilizes fluorogenic gene-specific hybridization probes for detection of the amplified DNA.

This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of Giardia lamblia, Cryptosporidium hominis, and C. parvum, as well as Entamoeba histolytica infections. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decision. Positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive cause of patient illness. Negative results in the setting of clinical illness compatible with gastroenteritis and/or colitis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as colitis, irritable bowel syndrome, or Crohn's disease.

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.

510(k) Summary

BD MAX™ Enteric Parasite Panel

Summary Preparation Date:

01/21/2022

Submitted by:

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Contact:

Joseph Basore, Ph.D., RAC
Staff Regulatory Affairs Specialist
Tel: 616-301-4068
Email: Joseph.Basore@bd.com

Proprietary Names:

For the instrument:

BD MAX™ System

For the assay:

BD MAX™ Enteric Parasite Panel

Common Names:

For the instrument:

Bench-top molecular diagnostics workstation

For the assay:

Enteric Parasite Nucleic Acid Test
Enteric Parasite identification and differentiation system
Enteric assay
Enteric test

Regulatory Information

Regulation section:

866. 3990 - Gastrointestinal microorganism multiplex nucleic acid-based assay

Classification:

Class II

Panel:

Microbiology (83)

Product Code(s):

PHC Gastrointestinal Pathogen Panel Multiplex Nucleic Acid-Based Assay System
OOI Real Time Nucleic Acid Amplification System

Predicate Device

BD MAX™ Enteric Parasite Panel (K143648)

Device Establishment

Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152
Registration Number: 1119779

Performance Standards

Class II Special Controls Guideline: Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens, November 2, 2015.

Intended Use

The BD MAX™ Enteric Parasite Panel performed on the BD MAX™ System is an automated *in vitro* diagnostic test for the direct qualitative detection of enteric parasitic pathogens. The BD MAX™ Enteric Parasite Panel detects nucleic acids from:

- *Giardia lamblia*
- *Cryptosporidium (C. hominis and C. parvum only)*
- *Entamoeba histolytica*

Testing is performed on unpreserved or 10% formalin-fixed stool specimens or FecalSwab™ specimens from symptomatic patients with suspected gastroenteritis, enteritis or colitis. The assay is intended to aid in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation and other laboratory findings. The test is performed directly on the specimen, utilizing real-time polymerase chain reaction (PCR) for the amplification of specific targets. The test utilizes fluorogenic gene-specific hybridization probes for detection of the amplified DNA.

This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of *Giardia lamblia, Cryptosporidium hominis, and C. parvum*, as well as *Entamoeba histolytica* infections. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decision. Positive results do not rule out co-infection with other organisms that are not detected by this test and may not be the sole or definitive cause of patient illness. Negative results in the setting of clinical illness compatible with gastroenteritis and/or colitis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.

Special Conditions for Use Statement: For Prescription Use Only

Special Instrument Requirements: BD MAX™ Enteric Parasite Panel is performed on the BD MAX™ System

Device Description

The BD MAX™ Enteric Parasite Panel assay along with the BD MAX™ System 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™ Enteric Parasite Panel, a test result may be called 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™ Enteric Parasite Panel is designed for use with unpreserved or 10% Formalin preserved stool samples or FecalSwab™ specimens. Unpreserved samples are placed in a BD MAX™ sample buffer tube (SBT) with a 10 µL transfer loop for analysis on the BD MAX™ System. The current 10% Formalin preserved specimen claim utilizes a plastic paddle (scoop) to place a stool sample into 15 ml of 10% Formalin media for transport before being placed into a SBT with a 10 µL transfer loop prior to analysis on the BD MAX™ System.

To use the FecalSwab™ Collection, Transport, and Preservation System, the operator transfers fecal material from an unpreserved stool specimen to the FecalSwab™ transport medium tube using the nylon flocked specimen collection swab. The FecalSwab™ transport medium tube is filled with 2 ml of a semi-solid medium that is designed to maintain the viability of enteric pathogenic bacteria during transit to the testing laboratory. Last, before analysis on the BD MAX™ System, samples collected/stored with the FecalSwab™ system are vortexed and then pipetted (150 µl) into a BD MAX™ sample buffer tube (SBT).

Once specimens (Unpreserved, 10% Formalin, or FecalSwab) are placed into a BD MAX™ SBT, the principles of the test are as described in K143648. For all specimen types the SBTs are heated on the BD Prewarm heater to facilitate lysis of the parasite organisms. Following heating, the SBTs are vortexed and then loaded into the BD MAX™ System along with the Unitized Reagent Strips, Master Mix, Extraction Tubes, and PCR Cartridges. No further operator intervention is necessary, and the automated procedures begin.

Microbial cells are lysed and DNA is extracted using a combination of lytic and extraction reagents at elevated temperatures. 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 high pH in elution buffer. Eluted DNA is neutralized and transferred to the Master Mix Tube to rehydrate the PCR reagents. After reconstitution, the BD MAX™ System dispenses a fixed volume of PCR-ready solution containing the extracted nucleic acids into the PCR Cartridge. Microvalves in the cartridge are sealed by the system prior to initiating PCR to contain the amplification mixture and thus preventing evaporation and contamination.

The amplified DNA targets are detected using hydrolysis (TaqMan®) 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 (amplicons) for enteric parasite targets and the Sample Processing Control in four 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™ Enteric Parasite 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 analyte (i.e., positive or negative). The assay includes a Sample Processing Control, which monitors the integrity of the reagents as well as the process steps involved in DNA extraction, amplification and detection, and checks for the presence of potential assay inhibitors.

Substantial Equivalence[1]

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

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

Table 1: Comparison of BD MAX™ Enteric Parasite Panel with FecalSwab to Predicate Device

Item	Predicate - BD MAX™ Enteric Parasite Panel (K143648)	Proposed - BD MAX™ Enteric Parasite Panel with Copan FecalSwab™ Collection, Preservation, and Transport System
Intended Use	The BD MAX™ Enteric Parasite Panel performed on the BD MAX™ System is an automated *in vitro* diagnostic test for the direct qualitative detection of enteric parasite pathogens. The BD MAX™ Enteric Parasite Panel detects nucleic acids from: • *Giardia lamblia* • *Cryptosporidium (C. hominis and C. parvum only)* • *Entamoeba histolytica* Testing is performed on unpreserved or 10% formalin-fixed stool specimens from symptomatic patients with suspected gastroenteritis, enteritis or colitis. The test is intended to aid in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation and other laboratory findings. The test is performed directly on the specimen, utilizing real-time polymerase chain reaction (PCR) for the amplification of specific targets. The test utilizes fluorogenic gene-specific hybridization probes for detection of the amplified DNA. This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of *Giardia lamblia*, *Cryptosporidium hominis* and *C. parvum*, as well as *Entamoeba histolytica* infections. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decision. Positive results do not rule out co-infection with other organisms that are not detected by this test,	The BD MAX™ Enteric Parasite Panel performed on the BD MAX™ System is an automated *in vitro* diagnostic test for the direct qualitative detection of enteric parasitic pathogens. The BD MAX™ Enteric Parasite Panel detects nucleic acids from: • *Giardia lamblia* • *Cryptosporidium (C. hominis and C. parvum only)* • *Entamoeba histolytica* Testing is performed on unpreserved or 10% formalin-fixed stool specimens or FecalSwab™ specimens from symptomatic patients with suspected gastroenteritis, enteritis or colitis. The assay is intended to aid in the diagnosis of gastrointestinal infection when used in conjunction with clinical evaluation and other laboratory findings. The test is performed directly on the specimen, utilizing real-time polymerase chain reaction (PCR) for the amplification of specific targets. The test utilizes fluorogenic gene-specific hybridization probes for detection of the amplified DNA. This test is intended for use, in conjunction with clinical presentation, laboratory findings, and epidemiological information, as an aid in the differential diagnosis of *Giardia lamblia, Cryptosporidium hominis, and C. parvum*, as well as *Entamoeba histolytica* infections. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decision.

Item	Predicate - BD MAX™ Enteric Parasite Panel (K143648)	Proposed - BD MAX™ Enteric Parasite Panel with Copan FecalSwab™ Collection, Preservation, and Transport System
	and may not be the sole or definitive cause of patient illness. Negative results in the setting of clinical illness compatible with gastroenteritis and/or colitis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.	Positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. Negative results in the setting of clinical illness compatible with gastroenteritis and/or colitis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease.
Organisms Detected	• *Giardia lamblia* • *Cryptosporidium (C. hominis and C. parvum only)* • *Entamoeba histolytica*	Same
Specimen Type	Unpreserved stool or 10% formalin-fixed	Unpreserved stool or 10% formalin-fixed or FecalSwab specimens
Assay Format	Amplification: PCR Detection: Fluorogenic target-specific hybridization	Same
Mode of Detection	Presence of • SSU rRNA gene specific for *Giardia lamblia* • sequence contained within the Laxer locus specific for *Cryptosporidium (C. hominis and C. parvum only)* • SSU rRNA gene specific for *Entamoeba histolytica*	Same
Interpretation of Test Results	Automated (BD MAX™ System diagnostic software)	Same
Analysis Platform	BD MAX™ System	Same
PCR Sample Preparation	Automated by the BD MAX™ System	Same
Detection Probes	TaqMan®Probe	Same
Assay Controls	Sample Processing Control (SPC)	Same

Item	Predicate - BD MAX™ Enteric Parasite Panel (K143648)	Proposed - BD MAX™ Enteric Parasite Panel with Copan FecalSwab™ Collection, Preservation, and Transport System
Preservation Buffer Formulation	Formalin-fixed: 10 % Formalin Unpreserved: None	Formalin-fixed: Same Unpreserved: Same FecalSwab: • Sodium Chloride • Calcium Chloride • Phosphate Buffer • L-Cysteine • Agar • Water
Preservation Buffer Container	• Formalin-fixed: Plastic Container w/Lid prefilled 15 ml of media. • Unpreserved: Not Applicable	• Formalin-fixed: Plastic Container w/Lid prefilled 15 ml of media. • Unpreserved: Not Applicable • FecalSwab: Plastic Container w/Lid prefilled 2 ml of media
Transfer Tool to Preservation Buffer	• Formalin-fixed: Plastic Paddle • Unpreserved: Not Applicable	• Formalin-fixed: Plastic Paddle • Unpreserved: Not Applicable • FecalSwab: Flocked Swab
Transport Method to SBT Tube	• Formalin-fixed: 10 µL Transport Loop • Unpreserved: 10 µL Transport Loop	• Formalin-fixed: Same • Unpreserved: Same • FecalSwab: 150 µL Pipette
Sterile	• Formalin-fixed: Not Applicable • Unpreserved: Not Applicable	• Formalin-fixed: Same • Unpreserved: Same • FecalSwab: Yes, Irradiation

Performance Evaluation

Four studies were conducted to demonstrate the substantial equivalence between the predicate specimen collection (Unpreserved) and the additional specimen collection (FecalSwab) for use in the BD MAX™ Enteric Parasite Panel assay:

- A study was performed to confirm equivalent analytical sensitivity with the FecalSwab. This study demonstrates that the LoD for FecalSwab fecal specimens is similar to the LoD of unpreserved stool specimens. The same LoD values were obtained for the unpreserved specimens in this study versus FecalSwab specimen for each of the three targets, *Entamoeba histolytica*, *Cryptosporidium parvum* and *Giardia lamblia,* indicating the analytical sensitivity is equivalent.

- Stability of stool specimens collected with the FecalSwab was tested against all target organisms. The results showed that the stability of FecalSwab specimens meets the current BD MAX™ Enteric Parasite Panel claims. For each organism tested across the BD MAX™ Enteric Parasite Panel, a detection ≥ 95% occurred at all the target stability time points claimed in the package insert. Therefore, stool preserved with FecalSwab can be stored for 48 hours (2 days) at 25 ± 2 °C and 120 hours (5 days) at 2 - 8 °C, and sample buffer tube inoculated with FecalSwab specimen can be stored for 48 hours (2 days) at 25 ± 2 °C and 120 hours (5 days) at 2 - 8 °C.

- A user variability study was performed to determine if the transfer of unpreserved stool to FecalSwab tubes by different users induced variability. The preparation of unpreserved stool panels prior to FecalSwab transfer and all steps subsequent to FecalSwab preparation, including the transfer to SBTs from each FecalSwab, were performed by a single experienced BD MAX™ user. The data demonstrate that expected assay results are obtained when FecalSwab stool specimens were prepared by multiple users.

- A comparison study of retrospectively collected clinical specimens was performed using the cleared collection device (unpreserved) and the new collection device (FecalSwab) with the BD MAX™ Enteric Parasite Panel on the BD MAX™ System. The results of this study, along with evaluation of contrived clinical specimens, where applicable, demonstrated that performance of the BD MAX™ Enteric Parasite Panel assay with the FecalSwab specimen type is comparable to the unpreserved stool specimen type.