K 052481

NOV 25 2005

510(k) SUMMARY

SUBMITTED BY:	BECTON, DICKINSON AND COMPANY 7 LOVETON CIRCLE SPARKS, MD 21152
CONTACT NAME: **TELEPHONE:**	Colleen A. Kistler 410-316-4988
PREPARED:	September 8, 2005
DEVICE NAME:	BD ProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays BD Viper™ System
PREDICATE DEVICES:	BD ProbeTec™ ET System as cleared with the BD ProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays (K984631) BD Viper™ Instrument (K023955)

INTENDED USE:

The BD ProbeTec ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays, when tested with the BD ProbeTec ET System, use Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis*, *N. gonorrhoeae*, or of co-infection with both *C. trachomatis* and *N. gonorrhoeae*. Specimens may be from symptomatic or asymptomatic females and males. A separate Amplification Control is an option for inhibition testing (BD ProbeTec ET CT/GC/AC Reagent Pack). The BD ProbeTec ET CT/GC assays may be performed using either the BD ProbeTec ET System or a combination of the BD ProbeTec ET System and BD Viper instrument.

The BD Viper System, when used with BD ProbeTec™ ET amplified nucleic assay(s) is intended for the *in vitro* detection of targeted organisms from specimens as identified in the assay-specific reagent package insert(s).

DEVICE DESCRIPTION:

The BD ProbeTec ET CT/GC Amplified DNA Assays utilize homogeneous SDA technology as the amplification method and fluorescent energy transfer (ET) as the detection method to test for the presence of CT and GC DNA in clinical specimens.

The BD Viper System is comprised of a standalone lysing heater and a BD Viper Instrument. The BD Viper Instrument is comprised of five major subsystems: robotic pipetting arm, priming and warming heaters (two sets), liquid crystal display (LCD) monitor with touch screen, instrument software and two thermally controlled fluorescent readers.

SUBSTANTIAL EQUIVALENCE:

This Special 510(k) is submitted for modifications to the subsystems previously cleared with the BD ProbeTec ET System (K984631) and the BD Viper Instrument (K023955). The BD Viper System is comprised of a standalone lysing heater and a BD Viper Instrument that combines the thermal, pipetting and optical subsystems from the previously cleared devices. Thus, there is no technology or intended use change associated with the device modification.

Modifications to the subsystems previously cleared with the BD ProbeTec ET System and BD Viper Instrument are as follows:

Modification	**Potential Impact of Modification**
Incorporated upgraded robot arm and controller	Hardware, Pipettor, Software
Lysing Heater and Lysing Rack dimensions modified to accommodate tube spacing on the BD Viper Instrument	Hardware, Thermal. Clinical Performance
Two BD ProbeTec ET thermally controlled optical reader assemblies repackaged and incorporated into the BD Viper Instrument	Hardware, Optics, Thermal, Software, Clinical Performance
Single function warming heater replaced with a dual-function reader subsystem	Hardware, Thermal, Software, Clinical Performance
Processing/Workflow Modifications	Pipettor, Hardware, Software, Clinical Performance
User Software Modifications	Software

The risk analysis did not identify these changes as raising new issues of safety and effectiveness. The parameters listed below were evaluated in studies comparing the BD Viper System to the BD ProbeTec ET System or to expected results (spiked specimen studies). The BD ProbeTec ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays were used to evaluate clinical performance. The BD Viper System met acceptance criteria for all parameters.

Parameter	Result
Lysing Heater	The BD Viper System met operating specifications across various environmental conditions.
Optical Linearity	The BD Viper System met optical and linearity specifications.
Hardware Environmental	The BD Viper System met thermal, pipetting, and optical specifications across various environmental conditions.
Instrument Contamination	The BD Viper System met specifications with regard to control and experimental conditions.
System Environmental	The BD Viper System met expected results with BD ProbeTec ET CT/GC controls (i.e., positive, negative) across various environmental conditions.
Analytical Limit of Detection (Diluent)	The BD Viper System had an equivalent analytical limit of detection to the BD ProbeTec ET System for both the BD ProbeTec ET CT and GC assays in a clean system matrix (i.e., BD ProbeTec ET diluent).
Precision	The precision of the BD Viper instrument was established and met expected results (i.e. positive, negative) for the BD ProbeTec ET CT/GC assays.
Analytical Limit of Detection (Clinical Matrices)	The BD Viper System had an equivalent analytical limit of detection to the BD ProbeTec ET System for both BD ProbeTec ET CT/GC assays in clinical matrices.
Individual Spiked Specimen	The BD Viper System met expected results (i.e., positive, negative) for the BD ProbeTec ET CT/GC assays.
Clinical Agreement	The BD ProbeTec ET CT/GC assay performance was equivalent between the BD Viper System and the BD ProbeTec ET System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 25 2005

Ms. Colleen A Kistler
Regulatory Affairs Specialist
BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: k052481
Trade/Device Name: BD Viper™ System
Regulation Number: 21 CFR 866.3390
Regulation Name: Neisseria spp. direct serological test reagents
Regulatory Class: Class II
Product Code: LSL
Dated: November 15, 2005
Received: November 16, 2005

Dear Ms. Kistler:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052481

Device Name: BD ProbeTec™ ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays

BD Viper™ System

Indications For Use:

The BD ProbeTec ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays, when tested with the BD ProbeTec ET System, use Strand Displacement Amplification (SDA) technology for the direct, qualitative detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in endocervical swabs, male urethral swabs, and in female and male urine specimens as evidence of infection with *C. trachomatis*, *N. gonorrhoeae*, or of co-infection with both *C. trachomatis* and *N. gonorrhoeae*. Specimens may be from symptomatic or asymptomatic females and males. A separate Amplification Control is an option for inhibition testing (BD ProbeTec ET CT/GC/AC Reagent Pack). The BD ProbeTec ET CT/GC assays may be performed using either the BD ProbeTec ET System or a combination of the BD ProbeTec ET System and BD Viper instrument.

The BD Viper System, when used with BD ProbeTec™ ET amplified nucleic acid assays, is intended for the *in vitro* detection of targeted organisms from specimens as identified in the assay-specific reagent package insert(s).

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device Evaluation and Safety

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