SEP 12 2005

K 052224

510(k) SUMMARY

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
7 LOVETON CIRCLE
SPARKS, MD 21152

CONTACT: KATHRYN BABKA POWERS
TELEPHONE: (410) 316-4260

PREPARED: September 7, 2005

DEVICE NAME: BD ProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays

BD ProbeTec™ Urine Preservative Transport (UPT)

PREDICATE DEVICE: BD ProbeTec™ Urine Processing Pouch (UPP) Kit as cleared with the BD ProbeTec ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assays (K984631)

INTENDED USE:

The BD ProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrohoeae* Amplified DNA Assays, when tested with the BD ProbeTec ET System, uses 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* and *N. gonorroheae*, or of co-infection with both *C. trachomatis* and *N. gonorroheae*. Specimens may be from symptomatic and 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 the BD Viper™ instrument.

The BD ProbeTec™ Urine Preservative Transport Kit with NAP Guard™ technology is designed to preserve and transport *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in male and female urine specimens from symptomatic and asymptomatic individuals prior to processing for analysis with the BD ProbeTec ET *C. trachomatis* (CT) and *N. gonorrhoeae* (GC) Amplified DNA Assays.

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 in clinical specimens.

The BD ProbeTec Urine Preservative Transport Kit with NAP Guard technology allows for an extended range of time and temperature conditions for specimen storage and transport when testing for the presence of *Chlamydia trachomatis* and *Neisseria gonorrohoeae* in urine specimens using the BD ProbeTec ET CT and GC Amplified DNA Assays. Each UPT contains 50 µL of NAP Guard (≥ 742.5 mM K_2EDTA) packaged with a disposable transfer pipette. Urine is transferred to the UPT tube, mixed with the tube contents and transported to the test site for processing according to the assay package insert.

SUBSTANTIAL EQUIVALENCE:

This Special 510(k) is submitted for modifications to the BD ProbeTec Urine Processing Pouch (UPP) originally cleared with the BD ProbeTec ET *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) Amplified DNA Assay (K984631). The modified device, the BD ProbeTec Urine Preservative Transport (UPT) is intended for use with female and male urine specimens from symptomatic or asymptomatic individuals for testing with the BD ProbeTec ET CT/GC Assays. No changes in intended use are being made to the BD ProbeTec ET CT/GC Amplified DNA Assays as a result of this modification.

Also included in this Special 510(k) is the addition of neat urine (urine without preservative) as a sample type with the CT/GC assays. Neat urine is a modification of the UPP device in that, under restricted urine transport and storage conditions and with a modification to the specimen processing procedure, use of the UPP may be eliminated from the CT/GC assay urine specimen processing procedure.

Modifications of the UPP device are as follows:

Modification	Potential Impact of Modification
Materials Modification	Specimen Stability
Input Specimen Volume Requirement	Sensitivity
Processing/Workflow Modification	Assay Interference

Risk analysis did not identify the changes as raising new issues of safety and effectiveness. The parameters listed below were evaluated in comparison studies of the UPT device and Neat urine sample type versus the UPP device. The UPT device and neat urine sample type met product claims for all parameters.

Parameter	Result
Analytical Limit of Detection	UPT and Neat urine sample types have analytical limits of detection equivalent to or better than UPP.
Interfering Substances	Potential interferents have no significant impact to positive and negative assay results with UPT and Neat urine sample types.
Specimen Stability	UPT specimen stability exceeds UPP specimen stability. Neat urine specimen stability is established.
Clinical Performance	UPT and Neat urine performance characteristics are equivalent to UPP.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 12 2005

Ms. Kathryn Babka Powers
Regulatory Affairs Specialist
BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: K052224
Trade/Device Name: BD ProbeTec™ ET CT/GC Amplified DNA Assays
Regulation Number: 21 CFR 866.3390
Regulation Name: *Neisseria* spp. direct serological test reagents
Regulatory Class: Class II
Product Code: LSL, MKZ
Dated: August 15, 2005
Received: August 16, 2005

Dear Ms. Powers:

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): K052224

Device Name: BD ProbeTec™ ET *Chlamydia trachomatis* and *Neisseria gonorrohoeae* Amplified DNA Assays

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

Office of In Vitro Diagnostic Device Evaluation and Safety

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