



K140447
510(k) Summary

BD Viper™ LT System

MAY 20 2014

Applicant BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152

Establishment Registration No. 1119779

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Summary Date May 15, 2014

Proprietary Name BD Viper™ LT System
Common Name BD Viper LT
Classification Class II
Classification Name Instrumentation for clinical multiplex test systems
Regulation Number 862.2570
Product Code OOI

Predicate Devices **BD Viper™ System (K081825)**

Device Description

The **BD Viper LT System** is a table-top instrument that is designed to be fully contained on a standard laboratory bench-top. The system performs automated extraction of nucleic acids from multiple specimen types in addition to amplification and detection of target nucleic acid sequences when utilized with legally marketed *in vitro* diagnostic assays.

Intended Use

The **BD Viper LT System** is intended for *in vitro* diagnostic (IVD) use in clinical laboratories to perform automated extraction of nucleic acids from multiple specimen types, amplification of target nucleic acid sequences by Strand Displacement Amplification (SDA) and detection of amplified nucleic acid using a two color fluorescence detection system. The **BD Viper LT** is for use only with *in vitro* diagnostic tests labeled for use on the system.

A comparison of the **BD Viper LT System** with the predicate **BD Viper System** is summarized below.



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BD Viper™ LT System

Table 1 Comparison to Predicate Device

	BD Viper System (K081825)	BD Viper LT System (K140447)
Intended Use	The BD Viper System, when used with the BD ProbeTec amplified nucleic assay(s), is intended for the <i>in vitro</i> detection of targeted organisms from specimens as identified in the assay-specific reagent package insert(s).	The BD Viper LT System is intended for <i>in vitro diagnostic</i> (IVD) use in clinical laboratories to perform automated extraction of nucleic acids from multiple specimen types, amplification of target nucleic acid sequences by Strand Displacement Amplification (SDA), and detection of amplified nucleic acids using a two color fluorescence detection system. The BD Viper LT is for <i>in vitro diagnostic</i> use only with tests labeled for use on the system
Technology	Strand Displacement Amplification (SDA)	Strand Displacement Amplification (SDA)
Assay Results	Qualitative	Qualitative

Instrument Specifications

Internal studies were conducted to validate the instrument specifications presented in **Tables 2-3**.



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Table 2 Thermal Specifications

Pre-warm heater fluid temperature	100°C >=9 min. not to exceed 115°C > 8 min
Priming heater fluid temperature	70°C ±2.0°C
Amplification heater fluid temperature	52.5°C ± 1.0°C
Temperature Accuracy: ±0.75°C; Temperature Uniformity: ±0.75°C	

Table 3 Optical Specifications

WaveLength	Set 1 (Green Channel)	Set 2 (Orange Channel)
Excitation	460-480 nm	575-597 nm
Emission	505-515 nm	610-630 nm
Maximum optical crosstalk ≤ 0.5%		
Set 1: Fluorescent dyes detected in this channel include: FAM		
Set 2: Fluorescent dyes detected in this channel include: ROX		

Clinical Performance Characteristics

Clinical utility of the BD Viper LT System was assessed during clearance of the BD ProbeTec GCQ Amplified DNA Assay as presented in a separate premarket submission (K140448).

Conclusions

The submitted information for the BD Viper LT System supports the determination of substantial equivalence in accordance with the intended use as stated in the product labeling.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

BECTON, DICKINSON AND COMPANY
SHERMA WINSTON, M.S.
REGULATORY AFFAIRS PROJECT MANAGER
7 LOVETON CIRCLE
SPARKS MD 21152

May 20, 2014

Re: K140447

Trade/Device Name: BD Viper LT System
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: II
Product Code: OOI
Dated: February 20, 2014
Received: February 21, 2014

Dear Ms. Winston:

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. 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 Parts 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

John  -S for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140447

Device Name
BD Viper™ LT System

Indications for Use (Describe)

The BD Viper LT System is intended for in vitro diagnostic (IVD) use in clinical laboratories to perform automated extraction of nucleic acids from multiple specimen types, amplification of target nucleic acid sequences by Strand Displacement Amplification (SDA) and detection of amplified nucleic acid using a two color fluorescence detection system. The BD Viper LT is for use only with in vitro diagnostic tests labeled for use on the system.

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)

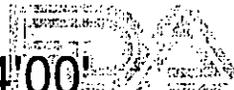
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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

John Hobson -S

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