K020810

OCT 03 2002

Section J. 510(k) Summary

Applicant Name and Address

Applicant: bioMerieux, Inc.
Address: 595 Anglum Road
Hazelwood, MO 63042

Contact Person: Sandra Perreand
Phone Number: (314) 731-8594
Fax Number: (314) 731-8689

Date of Preparation: September 25
., 2002

Device Name

Trade Name: VIDAS D-Dimer New (DD2) Assay
Common Name: Enzyme-linked Fluorescent Immunoassay (ELFA) for the quantitative detection of fibrin degradation products (FbDP)
Classification Name: 21 CFR

Predicate Device

Trade Name: VIDAS D-Dimer (DD) Assay
K972819

Device Description

The VIDAS® D-Dimer New (DD2) Assay is an automated quantitative test for use on the VIDAS instrument (K891385) for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma using the enzyme-linked fluorescent immunoassay (ELFA) technique. The instrument controls all assay steps and assay temperatures. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR), serves as the solid phase as well as a pipettor for the assay. Reagents for the assay are ready-to-use and pre-dispensed in the sealed DD2 Reagent Strips.

The assay principle combines a two-step enzyme immunoassay sandwich method with a final fluorescent detection (ELFA). The Solid Phase Receptacle (SPR) serves as the solid phase with the anti-FbDP monoclonal (mouse) antibodies P10B5E12C9 adsorbed on its surface, as well as the pipetting device for the assay.

The instrument performs all of the assay steps automatically. The reaction medium is cycled in and out of the SPR several times according to a specified protocol.

The sample is taken and transferred into the well containing the conjugate, which is an alkaline phosphatase-labeled anti-FbDP monoclonal (mouse) antibodies (P2C5A10). The sample/conjugate mixture is cycled in and out of the SPR several times to increase the reaction speed. The antigen binds to antibodies coated on the SPR and to the conjugate forming a "sandwich".

In the second step, the remaining free antigen sites are saturated by cycling the conjugate in the fifth well of the strip in and out of the SPR. Unbound components are eliminated during the washing steps.

Two detection steps are then performed successively. During each step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The conjugate enzyme catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm. The intensity of the fluorescence is proportional to the concentration of antigen present in the sample.

At the end of the assay, results are automatically calculated by VIDAS in relation to two calibration curves stored in memory corresponding to the two detection steps. A threshold signal determines the choice of the calibration curve to be used for each sample. The results are then printed out.

Intended Use
The VIDAS D-Dimer New assay is intended for use as an aid in the diagnosis of deep venous thrombosis and pulmonary embolism disease.

Technological Characteristic Summary

Summary of Similarities and Differences to Predicate Device

Major Similarities Include:

1) Both assays are fully automated, quantitative enzyme-linked fluorescent immunoassays (ELFA) that detect fibrin degradation products (FbDP) in plasma (trisodium citrate).

2) Both assays use alkaline phosphatase as a conjugate and 4-methylumbelliferyl phosphate as a fluorescent substrate.

3) Both assays are designed for use with the VIDAS or miniVidas instruments. When either assay is complete, the instrument's computer analyzes the results automatically.

4) All reagents are identical in composition with the exception of the new C1 control and S1 calibrator.

Major Differences Include:

1) The DD2 Assay kit includes two controls instead of 3 controls as in the original DD Assay. The C1 and C3 controls were replaced with a new C1 control for the DD2 Assay.

2) The DD2 Assay kit includes two calibrators instead of one calibrator as in the original DD Assay. S2 from the DD2 Assay is equivalent to S1 in the original DD Assay. A new S1 was added for the DD2 Assay.

3) The DD2 Assay uses two master curves instead of one curve used by the original DD Assay. For each curve of the DD2 Assay, there is one calibrator and one control. The S2 calibrator and C2 control are used for concentrations in the range of 0 – 1000 ng/mL. The S1 calibrator and C1 control are used for concentrations in the range of 1000 – 10000 ng/mL.

4) Samples for use with the DD2 Assay may be stored at 2 - 8°C for up to 24 hours or 2 months at -20°C. Samples for use with the DD Assay must be tested within 4 hours of collection.

5) The VIDAS D-Dimer New assay has an assay range of 45-10,000 ng/ml, while the DD assay has an assay range of 45-1,000 ng/ml.

Performance Data

Ninety-three samples were tested using the VIDAS D-Dimer New (DD2) Assay and the VIDAS D-Dimer (DD) Assay on the VIDAS instrument. Real plasma samples were used unless spiked samples were necessary to achieve higher levels of D-Dimer concentration. The correlation plot for the entire range of samples (93 samples total), 0 – 10,000 ng/mL, shows a slope of 0.9994, ordinate of 42.972 and a correlation coefficient of 0.9832. The correlation plot for the values less than 1000 ng/mL (35 samples total) shows a slope of 1.0094, ordinate of –21.917 and a correlation coefficient of 0.9816.

The study conducted at the outside facility also showed the results correlated well between the VIDAS DD2 and VIDAS DD Assays. For results of D-Dimer less than 1000 ng/mL, the slope was 1.193 with a correlation coefficient of 85.4%. For D-Dimer values between 1000 and 10000 ng/mL, the slope was 0.891 with a correlation coefficient of 85.7%. With respect to clinical sensitivity, specificity, and negative predictive value the results are as outlined below.

For subjects suspected of pulmonary embolism, the following results were obtained:

	DD2 Assay	**DD Assay**
Sensitivity	100% (95% CI, 90-100)	97.1 % (95% CI, 85.5-99.9)
Specificity	35.9% (95% CI, 27.2-44.6)	42.7 % (95% CI, 33.8-51.7)
Negative Predictive Value	100% (95% CI, 91.6-100)	98.0% (95% CI, 89.6-99.9)

Note: One false negative was obtained with the DD Assay.

For subjects suspected of deep venous thrombosis, the following results were obtained:

	DD2 Assay	**DD Assay**
Sensitivity	100% (95% CI, 90.5-100)	100 % (95% CI, 90.5-100)
Specificity	30.1% (95% CI, 21.6-38.5)	38.1 % (95% CI, 29.1-47.0)
Negative Predictive Value	100% (95% CI, 89.7-100)	100% (95% CI, 98.1-100)

For subjects suspected of venous thromboembolism (all subjects suspected of having DVT and PE), the following results were obtained:

	DD2 Assay	**DD Assay**
Sensitivity	100% (95% CI, 95.0-100)	98.6 % (95% CI, 92.5-100)
Specificity	33.0% (95% CI, 27.0-39.1)	40.4 % (95% CI, 34.1-46.8)
Negative Predictive Value	100% (95% CI, 95.3-100)	98.9% (95% CI, 94.2-100)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 0 3 2002

Ms. Sandra Perreand
Director, Regulatory Affairs
BioMerieux, Inc.
595 Anglum Road
Hazelwood, Missouri 63042-2320

Re: k020810
Trade/Device Name: VIDAS D-Dimer New (DD2) Assay
Regulation Number: 21 CFR § 864.7320
Regulation Name: Fibrin Degradation Products Assay
Regulatory Class: II
Product Code: DAP
Dated: August 12, 2002
Received: August 13, 2002

Dear Ms. Perreand:

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 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); 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.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K020810

Device Name: VIDAS D-Dimer New (DD2) Assay

Indications for Use:
The VIDAS® D-Dimer New assay indicated for use as an aid in the diagnosis of deep venous thrombosis and pulmonary embolism disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices K020810
510(k) Number

✓ Prescription